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Canada Vigilance AER#:	E2B_04632965 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210903 CCYYMMDD
	HC Initial Received Date:	20210903 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-299502(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210826 CCYYMMDD	20210826 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2021-299502

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
irms QMODERNAP	CA-irms-MOD21-135818 CA-MODERNATX, INC.-MOD-2021-299502

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			40 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RECENTLY DIED TWO WEEKS AFTER HIS SECOND MODERNA JAB

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of DEATH (recently died two weeks after his second Moderna jab) in a 40-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination.

Concurrent medical conditions included Non-smoker.

On an unknown date, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

No treatment drug information provided.

No concomitant drug information provided.

Patient did not drink. Gender was not confirmed but patient referred to as his and he.

Very limited information regarding this event has been provided at this time. Further information has been requested if possible.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Very limited information regarding this event has been provided at this time. Further information has been requested if possible.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Non-smoker

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220520 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A714754()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210906 CCYYMMDD	20220518 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A714754

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada MC Canada Safety Report ID AZPROD0000	000949763 [redacted] CA-DHPR-20210513150830_7001 CA-AstraZeneca-2021A714754

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			55 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Abdominal pain
26.0	Abnormal behaviour
26.0	Anxiety
26.0	Aphasia
26.0	Cerebral thrombosis
26.0	Discoloured vomit
26.0	Electric shock sensation
26.0	Headache
26.0	Malaise
26.0	Neurological symptom
26.0	Pain
26.0	Platelet count decreased
26.0	Pulmonary embolism
26.0	Pulmonary infarction
26.0	Speech disorder
26.0	Thrombosis
26.0	Vomiting

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 1 ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021 CCYY		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Off label use ,		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

APHASIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Aphasia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Aphasia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PULMONARY EMBOLISM

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary embolism		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Pulmonary embolism		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PULMONARY INFARCTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary infarction		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Pulmonary infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PLATELET COUNT DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Platelet count decreased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Platelet count decreased

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SPEECH DISORDER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Speech disorder
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Speech disorder

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombosis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VOMITING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vomiting
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vomiting

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Abdominal pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Abdominal pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABNORMAL BEHAVIOUR

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Abnormal behaviour		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Abnormal behaviour		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ANXIETY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Anxiety		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Anxiety		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DISCOLOURED VOMIT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Discoloured vomit		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Discoloured vomit		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ELECTRIC SHOCK SENSATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Electric shock sensation		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Electric shock sensation		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

MALAISE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Malaise		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Malaise		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NEUROLOGICAL SYMPTOM

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Neurological symptom		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Neurological symptom		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ASTRAZENECA COVID 19 VACCINE INDICATED FOR PROPHYLAXIS (OFF LABEL USE)

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Off label use		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Off label use		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer via the regulatory authority in Canada (Health Canada) concerning a female patient of an unknown ethnic origin (age 55 years).

The patient's past and current medical history included period cramps (dates not reported) in past but not for a few years. The patient was generally healthy. The fibroid was pre-existing for thirty years.

No concomitant products were reported.

During 2021, the patient received first dose of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN) once/single administration, via intramuscular route, for infection prevention.

The report described off-label use for Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. The reported term was "astrazeneca covid 19 vaccine indicated for prophylaxis (off label use)".

On an unknown date, the patient experienced aphasia (preferred term: Aphasia), pulmonary embolism (preferred term: Pulmonary embolism), cerebral thrombosis (preferred term: Cerebral thrombosis), pulmonary infarction (preferred term: Pulmonary infarction), pain (preferred term: Pain), platelet count decreased (preferred term: Platelet count decreased), speech disorder (preferred term: Speech disorder), thrombosis (preferred term: Thrombosis), vomiting (preferred term: Vomiting), abdominal pain (preferred term: Abdominal pain), abnormal behaviour (preferred term: Abnormal behaviour), anxiety (preferred term: Anxiety), discoloured vomit (preferred term: Discoloured vomit), electric shock sensation (preferred term: Electric shock sensation), headache (preferred term: Headache), malaise (preferred term: Malaise), neurological symptom (preferred term: Neurological symptom), astrazeneca covid 19 vaccine indicated for prophylaxis (off label use) (Preferred term: Off label use). The reporter stated that twenty hours after the vaccine, developed severe headache, lightening bolts to brain. She self-treated herself with Advil, twenty-four hours post-vaccine, she developed abdominal pain like knives to abdomen. She was in pain and not acting like herself. The headache and abdominal pain continued for a number of days, she then thought she was better and she stopped taking Advil, however, she got worse. Twenty-four hours before death, she felt like she was going to vomit. Then she vomited for two hours and then felt unwell afterwards. Vomit was reddish in color and she thought it was from ketchup chips. She had clotting which led to death. The reporter stated that there were neurological signs before death like mumbling and loss of speech and there was a clot in her brain as well. The patient died before reaching the hospital. Post-mortem COVID-19 test was negative. There was a low platelet count in post-mortem blood test.

The action taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable.

During 2021, the patient died from the event of aphasia, pulmonary embolism, cerebral thrombosis, pulmonary infarction, pain, platelet count decreased, speech disorder, thrombosis, vomiting, abdominal pain, abnormal behaviour, anxiety, discoloured vomit, electric shock sensation, headache, malaise and neurological symptom. The outcome of the event of astrazeneca covid 19 vaccine indicated for prophylaxis (off label use) was unknown.

An autopsy was performed which showed lung infarcts and pulmonary embolism as well as a fibroid. No blood clot was found in brain. The cause of death was aphasia, pulmonary embolism, cerebral thrombosis, pulmonary infarction, pain, platelet count decreased, speech disorder, thrombosis, vomiting, abdominal pain, abnormal behavior, anxiety, discoloured vomit, electric shock sensation, headache, malaise and neurological symptom.

The reporter assessed the events of aphasia, pulmonary embolism, cerebral thrombosis, pulmonary infarction, pain, platelet count decreased, speech disorder, thrombosis, vomiting, abdominal pain, abnormal behaviour, anxiety, discoloured vomit, electric shock sensation, headache, malaise and neurological symptom as serious due to seriousness criterion of death. The reporter assessed the events of aphasia, pulmonary embolism, cerebral thrombosis, pulmonary infarction, pain, platelet count decreased, speech disorder, thrombosis, vomiting, abdominal pain, abnormal behaviour, anxiety, discoloured vomit, electric shock sensation, headache, malaise and neurological symptom as serious due to seriousness criterion of important medical event. The reporter assessed the event of astrazeneca covid 19 vaccine indicated for prophylaxis (off label use) as non-serious.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Summary of follow-up information received by AstraZeneca/MedImmune 18-May-2022 from a consumer via spontaneous source: added reference reporter, added start date and indication for suspect, added relevant history period cramps and fibroids, added date of death and updated autopsy performed, added all lab tests. Narrative amended.CAUSE OF DEATH: APHASIA CAUSE OF DEATH: PULMONARY EMBOLISM CAUSE OF DEATH: CEREBRAL THROMBOSIS CAUSE OF DEATH: PULMONARY INFARCTION CAUSE OF DEATH: PAIN CAUSE OF DEATH: PLATELET COUNT DECREASED CAUSE OF DEATH: SPEECH DISORDER CAUSE OF DEATH: THROMBOSIS CAUSE OF DEATH: VOMITING CAUSE OF DEATH: ABDOMINAL PAIN CAUSE OF DEATH: ABNORMAL BEHAVIOUR CAUSE OF DEATH: ANXIETY CAUSE OF DEATH: DISCOLOURED VOMIT CAUSE OF DEATH: ELECTRIC SHOCK SENSATION CAUSE OF DEATH: HEADACHE CAUSE OF DEATH: MALAISE CAUSE OF DEATH: NEUROLOGICAL SYMPTOM Lab Test #1 : 10084356 Lab Test #2 : 10035525
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal events of aphasia, speech disorder, Vomiting, Abdominal pain, abnormal behavior, anxiety, discoloured vomit, electric shock sensation, Headache, Malaise and Neurological symptom are not listed in the company core data sheet of AZD1222.Thrombosis (PT: pulmonary embolism, Cerebral thrombosis, Pulmonary infarction, Thrombosis) in combination with thrombocytopenia (PT: platelet count decreased) are listed in the company core data sheet of AZD1222, however since they are reported with fatal outcome they become unlisted. The events aphasia and speech disorder could be associated with each other. The events thrombosis, cerebral thrombosis, pulmonary embolism and pulmonary infarction could be associated with each other. The events abnormal behavior, anxiety, electric shock sensation could be in association with each other. Cause of death is further specified as aphasia, pulmonary infarction, speech disorder, abnormal behavior, anxiety, discoloured vomit, electric shock sensation, neuroloogical symptom, thrombosis, cerebral thrombosis, pulmonary embolism, platelet count decreased, pain, vomiting, abdominal pain, headache, malaise. Due to limited information on circumstances leading to events, clinical course, other concurrent conditions, concomitant medications, other relevant medical and family history, specific risk factors (infection, neurological disorders, cardiac disorder, respiratory disorder, trauma, hypercholesterolemia, smoking),etiological and diagnostic workup (complete blood count, infection panel, liver function test, renal function test, lipid profile, imaging studies, clinical examination), the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	COVID-19 virus test	Negative	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Platelet count	low	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Menstrual cramps	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	No	

Comments (B.1.7.1g)
Had some period cramps in past but not for a few years

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fibroids	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	

Comments (B.1.7.1g)
pre-existing for thirty years

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Aphasia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pulmonary embolism	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Pulmonary infarction	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Pain	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Platelet count decreased	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Speech disorder	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Vomiting	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Abdominal pain	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Abnormal behaviour	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Anxiety	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Discoloured vomit	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Electric shock sensation	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Headache	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Malaise	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Neurological symptom	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	Health Canada
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04647082 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210908 CCYYMMDD	
	HC Initial Received Date: 20210908 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A716830()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210906 CCYYMMDD	20210906 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
NO	
	Company number (A.1.10.2) CA-AstraZeneca-2021A716830

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	E2B_04220040 [redacted] CA-AstraZeneca-2021A716830

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Thrombocytopenia
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a patient of unknown gender (age not provided) of Unknown ethnic origin.

No medical history was reported. No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN) 0.5 ml, via intramuscular route, on an unknown date. On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia), thrombosis (preferred term: Thrombosis).

The action taken with Covid-19 Vaccine Astrazeneca (chadox1-s (viral Vector)) was Not Applicable. The outcome of the events was fatal.

The patient died from the event of thrombocytopenia and thrombosis on an unspecified date.
It was not known whether an autopsy was performed. The cause of death was thrombocytopenia and thrombosis.

The events were considered serious thrombocytopenia and thrombosis (death, hospitalized and important medical event).

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 vaccine is an Astrazeneca Canada Inc. product authorized under the Interim Order.
CAUSE OF DEATH: THROMBOCYTOPENIA CAUSE OF DEATH: THROMBOSIS
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Thrombosis in combination with Thrombocytopenia is listed in the company core data sheet of AZD1222. However, since the events were reported with a fatal outcome they are considered unlisted. Due to limited information on patients age and gender, family and medical history, concurrent conditions (heart disease, deep venous thrombosis, traumatic injury, neoplastic disease, thrombophilia, chronic obstructive pulmonary disease), concomitant medication, further clarification of the events, details of the location of the thrombosis, specific risk factors and lifestyle (prolonged immobilization, smoking habit), etiological and diagnostic work up (physical findings, complete blood analysis, including D dimer test, autoimmune profile, viral serologies, ECG, chest and brain imaging studies, echocardiography, Venous Doppler Ultrasound), details on interventions and treatment, biopsy result, the evaluation did not find evidence to suggest a causal relationship between the events and vaccine AZD12222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) UNKNOWN	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) CANADIAN HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) Confidential
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_04647082 (0)	Page#6

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04649888 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210908 CCYYMMDD	
	HC Initial Received Date: 20210908 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A716879()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210906 CCYYMMDD	20210906 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
NO	Company number (A.1.10.2)
	CA-AstraZeneca-2021A716879

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADA HEALTH AUTHORITY MC CANADA AZPROD0000	E2B_04182614 [redacted] CA-AstraZeneca-2021A716879

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04649888 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Thrombocytopenia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombocytopenia

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Thrombocytopenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADA HEALTH AUTHORITY) via consumer concerning a patient of unknown gender, age and ethnic origin.

No medical history was reported. No concomitant products were reported.

The patient received AstraZeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5 ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN), via intramuscular route, on an unknown date. On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia).

Action taken with AstraZeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable. The patient died from the event thrombocytopenia on an unspecified date.

It is not known whether an autopsy was performed. The cause of death was thrombocytopenia.

The reporter considered the event of thrombocytopenia serious due to seriousness criteria of death and important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.CAUSE OF DEATH: THROMBOCYTOPENIA
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case report concerns a patient of unknown age who presented thrombocytopenia with fatal outcome after vaccine AZD1222 administration. Cause of death was reported as thrombocytopenia. Due to limited information on patient?s demographics, platelet count before vaccination, relevant medical history, concomitant medication, comorbidities, event details including detailed description on circumstances leading to the event, baseline health condition before vaccination, family history, diagnostic and etiological workup (complete blood panel with infectious profile, viral panel test including human deficiency virus and hepatitis panel, abdominal ultrasound with spleen evaluation, blood cultures, platelet factor 4 antibodies), discussion on lifestyle, specific risk factors and etiological factors (viral infections, hemolytic uremic syndrome, medication, bacteremia, alcoholism, bone marrow disorders, anemia), report of laboratory tests performed (including exact dates, units and normal rangees), details on interventions and treatment, medical notes from a health care provider, the evaluation did not find evidence to suggest a causal relationship between the event and vaccine AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Thrombocytopenia

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADA HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

From: Canada Vigilance (HC/SC)
Sent: 2021-05-12 12:17 PM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Cc: Harland, Claire (HC/SC)
Subject: PUB-001185 FW: Reporting a side effect to the Canada Vigilance Program

---

Importance: High

Categories: COVID

Hi EFAX,

For DE please. Once data entered, can we please obtain an AER number for this report for Claire (CC here)?

Thanks,
Chris

[redacted]

From: Canada Vigilance [redacted] (HC/SC) <hc.canada.vigilance.[redacted].sc@canada.ca>
Sent: 2021-05-12 11:23 AM
To: Canada.Vigilance.NCR-RCN (HC/SC) <hc.canada.vigilance.ncr-rcn.sc@canada.ca>
Cc: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Subject: FW: Reporting a side effect to the Canada Vigilance Program
Importance: High

Good morning,
Please see email below,
I spoke with this gentleman yesterday and I sent the link by email to report an AR to AstraZeneca vaccine (his wife died) and he requested:

1. Information of when (if) the AR was submitted by the coroner or doctor (I said that for private issues we cannot get access to that information but if he wasn't sure if was reported I said he could report too)
2. An ombudsman that could assist on his case (I said I'll send a request to my team leader)

Thank you,
Ausmar

From [redacted]
Sent: 2021-05-12 10:54 AM
To: Canada Vigilance [redacted] (HC/SC) <hc.canada.vigilance[redacted]sc@canada.ca>
Cc [redacted]
Subject: Re: Reporting a side effect to the Canada Vigilance Program

THIS IS THE WRONG FORM. I asked about reporting an adverse effect following immunization - a suspected vaccine related death following immunization. The form

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required is AEFI Adverse Effects Following Immunization.

I am trying to follow your web site instructions.

This case does not qualify under the heath product category you responded with below.

Please send appropriate form as you promised. I will then fill out as you advised for an adverse event Death linked or suspected to AstraZeneca-Oxford Covid-19 immunization.

So frustrated.

I advised by telephone message, and in our conversation both yesterday, that the MANDATORY (must) submittal of the form is an issue and is in question with our local body. My initial and MAIN request was confirmation of date and time that any such form was submitted - confirmation of if and when - This submitt date is secret and has become a nightmare with the local health region [redacted] via the local coroner's office. Confirmation of this date and time is still requested.

You advisd that the time and date can not be provided. But a duplicate AEFI form can be filled out by me with help from Health Canada Vigilence over the phone if necessary; the two reported forms can then be "merged" you said. Please send me the form,

ALSO I specifically asked in telephone message and to you on your return call for an OMBUDSMAN that could assist. You stated you would speak to supervisor and would reply. Please include that information with the form.

We expect clarity and transparency.

Reporting was to be expedient and timely to the national system.

No cover--up or secret agreements are acceptable on matters of timely national health importance.

I would prefer never to have questioned the integrity of the system - I read directly on your web site that the form must be submitted by a health professional only. You said not true.

Sorry for the long story - this is holding up burial of the deceased. A date and time to confirm job was done and vigilance system notified at time requested, on behalf of family should not be SECRET.

Please reply immediately.

Sincerely,

[redacted]

Death 2021

[redacted]

From: Canada Vigilance [redacted] (HC/SC) <hc.canada.vigilance [redacted] sc@canada.ca>
Sent: May 11, 2021 2:31 PM
To [redacted]
Subject: Reporting a side effect to the Canada Vigilance Program

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Greetings,

Thank you for your inquiry to report an adverse reaction on May 11, 2021.

Please find attached, as requested, a side effect reporting form.

Side effects suspected to be associated with a health product are important to Health Canada's post-market surveillance program, which monitors the safety profile of health products and ensures that the benefits of the products continue to outweigh the risks.

Completing a side effect reporting form is an effective way to record the suspected side effect, and provides the information that Health Canada needs to further assess the reaction.

Reporting a side effect to the Canada Vigilance Program can be done by one of the following ways:

- Report online at https://hpr-rps.hres.ca/side-effects-reporting-form.php?form=voluntary&lang=en
- Call toll free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax to 1-866-678-6789
  - Mail to: Health Canada
    Marketed Health Products Directorate
    Canada Vigilance Program
    Postal Locator 1908C
    Ottawa, Ontario K1A 0K9

Postage paid labels, the side effect reporting form and reporting guidelines are available at: www.health.gc.ca/medeffect.

We look forward to receiving your completed side effect reporting form. Should you have any other questions related to the reporting of side effects, or the Canada Vigilance Program, please do not hesitate to contact us.

Your contribution and commitment to health product safety monitoring are appreciated.

Canada Vigilance Office
Canada Vigilance Program
Health Canada

Canada

ATIA - 19(1)

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From: Canada Vigilance [redacted](HC/SC)
Sent: 2021-05-13 9:36 AM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Cc: Canada Vigilance (HC/SC); Harland, Claire (HC/SC)
Subject: FW: URGENT Fw: Adverse Reaction Receipt Number/le numéro d'effet indésirable: [RCT-20210512-1902][1]

Categories: COVID

Good morning EFAX,
Please attached the email below as a follow up to 000949763.
Thanks,
Ausmar

From: Zuniga, Alexie (HC/SC) <alexie.zuniga@canada.ca> **On Behalf Of** CV Systems / Systèmes (HC/SC)
Sent: 2021-05-13 7:07 AM
To: Canada Vigilance [redacted](HC/SC) <hc.canada.vigilance.[redacted]sc@canada.ca>
Subject: RE: URGENT Fw: Adverse Reaction Receipt Number/le numéro d'effet indésirable: [RCT-20210512-1902][1]

Hello,

Just wanted to confirm if the message has been forwarded to hc.canada.vigilance.sc@canada.ca?

From: [redacted]
Sent: 2021-05-12 2:50 PM
To: Canada Vigilance [redacted](HC/SC) <hc.canada.vigilance.[redacted]sc@canada.ca>
Cc [redacted] CV Systems / Systèmes (HC/SC) <hc.cv.systems-systemes.sc@canada.ca>
Subject: URGENT Fw: Adverse Reaction Receipt Number/le numéro d'effet indésirable: [RCT-20210512-1902][1]
Importance: High

Kind Sirs/Madam,

This report below was populated and submitted without my knowledge, it may not be incorrect (have not checked it fully) BUT it is specifically and directly the WRONG form.

The AEFI - Adverse Event Following Immunization form is required to be submitted NOT the form applicable to health products as defined (Drugs, health products, therapeutics) versus separate form completely for vaccines.

This is critical. Timely action is mandatory..

Please assist IMMEDIATELY with correct AEFI form.

ATIA - 19(1)

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See attached PDF or email yesterday for original info and the two additional formal requests not yet covered.

Also, product name must have the "AstraZeneca" portion of the name in its title - this is not a generic vaccine.

Sincerely,

[redacted]

From: hc.ar-ri-triage.sc@canada.ca <hc.ar-ri-triage.sc@canada.ca>
Sent: May 12, 2021 12:34 PM
To: hc.cv.systems-systemes.sc@canada.ca <hc.cv.systems-systemes.sc@canada.ca>;
[redacted]
Subject: Adverse Reaction Receipt Number/le numéro d'effet indésirable: [RCT-20210512-1902][1]

A French message will follow / Un message en français suivra

Dea[redacted]

Thank you for submitting an adverse reaction report to the Canada Vigilance Program. Your experience with marketed health products is important to us and we appreciate the time you took to report.

The information that you included in your report has been recorded in the Canada Vigilance Program database as follows:

Adverse Reaction Number: LRN-20210512-1302 0.0
Health Product Name (as reported): COVID-19 VACCINE
Please reference the above Adverse Reaction Number should you wish to report additional information on this event. Please note that Health Canada will contact you about your report only if additional information is required for its surveillance activities.

Please do not respond to this email. This account is not monitored. Please contact hc.canada.vigilance.sc@canada.ca with any questions or concerns.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products that have been submitted by manufacturers, by hospitals, or by health professionals and consumers either directly to Health Canada or via the manufacturers.

The information from adverse reaction reports as well as information from other sources of data is used to determine whether the benefits of a given health product continue to outweigh its risks and to take appropriate action to minimize any new risks. Such actions may include the update of the label of a health product in its authorized Canadian monograph, risk communication(s) to inform Canadians about possible new adverse reactions and/or a recall of the product.

For information on health products authorized for sale in Canada, you may wish to consult the following:

- Drug Product Database: https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
- Licensed Natural Health Products Database: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing/licensed-natural-health-products-database.html
- Canada Vigilance Adverse Reaction Online Database: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html
- Advisories, recalls and other communication on health products: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/stay-informed-medeffect-canada.html

We would like to thank you once again for your report, as your contribution and commitment to health product safety monitoring are appreciated.

Sincerely,

Canada Vigilance Program
Marketed Health Products Directorate
Health Canada

ATIA - 19(1)

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Cher / Chère [redacted]

Nous vous remercions d'avoir déclaré un effet indésirable au Programme Canada Vigilance. Votre expérience en lien avec les produits de santé commercialisés est une source d'information importante pour nous en matière d'innocuité, et nous vous remercions du temps que vous avez pris pour présenter cette déclaration.

Les renseignements que vous avez inclus dans votre déclaration ont été consignés dans la base de données du Programme Canada Vigilance comme suit :

Numéro de l'effet indésirable: LRN-20210512-1302 0.0

Nom du produit de santé (tel que déclaré): COVID-19 VACCINE

Veuillez indiquer le numéro d'effet indésirable ci-dessus si vous souhaitez fournir des renseignements supplémentaires sur cet événement. Veuillez noter que Santé Canada communiquera avec vous au sujet de votre déclaration seulement si des renseignements supplémentaires sont requis pour ses activités de surveillance.

Veuillez ne pas répondre à ce courriel. Ce compte n'est pas surveillé. Veuillez communiquer avec hc.canada.vigilance.sc@canada.ca pour toute question ou préoccupation.

Le Programme Canada Vigilance est le programme de surveillance après la mise en marché de Santé Canada qui recueille et évalue les déclarations d'effets indésirables présumés associés aux produits de santé soumises par des fabricants, des hôpitaux, des professionnels de la santé et des consommateurs directement à Santé Canada ou par l'entremise des fabricants.

Les renseignements tirés des déclarations d'effets indésirables et d'autres sources de données servent à déterminer si les avantages d'un produit de santé donné continuent de l'emporter sur ses risques et à prendre les mesures appropriées pour minimiser les nouveaux risques. Ces mesures peuvent comprendre la mise à jour de l'étiquette d'un produit de santé dans sa monographie canadienne autorisée, la communication des risques pour informer les Canadiens au sujet des nouveaux effets indésirables possibles et/ou le retrait du produit.

Pour obtenir des renseignements sur les produits de santé dont la vente est autorisée au Canada, vous pouvez consulter les pages Web suivantes :

- Base de données sur les produits pharmaceutiques: https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medicaments/base-donnees-produits-pharmaceutiques.html
- Base de données sur les produits de santé naturels homologués: https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/naturels-sans-ordonnance/demandes-presentations/licence-mise-marche/base-donnees-produits-sante-naturels-homologues.html
- Base de données en ligne des effets indésirables de Canada Vigilance: https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medeffet-canada/base-donnees-effets-indesirables.html
- Avis, retraits et autres communications sur les produits de santé: https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medeffet-canada/restez-informe-medeffet-canada.html

Nous vous remercions à nouveau pour votre déclaration. Votre contribution et votre participation à la surveillance de l'innocuité des produits de santé sont appréciées.

Cordialement,

Programme Canada Vigilance
Direction des produits de santé commercialisés
Santé Canada

ATIA - 19(1)

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Verbal report taken by RC Claire- note the husband feels that the coroner and [redacted] is putting incorrect info in his mouth and trying to sweep this under the rug and he wants someone from the government to enforce mandatory reporting/confirm receipt of report(likely went to PHAC?). I have flagged this higher and given him contact info for the food and drug liasion office/ombudsman as requested. He may have more info if needed, he mentioned he had lists of her symptoms from family members(though he was present the whole time), but he wanted answers on transparency and "vigilance" from CV/PHAC so may not want to discuss further without answers to those concerns.

Safety Report ID: CA-DHPR-20210513150830_7001

Type of Report: Follow-up

HC Ref. No: 000949763

Reporter File No.:

Transmission Date: 20210513

First Name: [redacted]

Last Name [redacted]

Telephone: [redacted]

Ext.:

Address:

City: [redacted]

Province/Territory [redacted]

Postal Code:

Email address:

Organization:

Reporter Type: Consumer or other non health professional

Patient ID: [redacted]

Age: 55 Year(s)

Sex: Female

Height:

Weight:

Med History: none, generally healthy. Had some period cramps in past but not for a few years

Allergies:

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Serious Death: Yes

Date of Death: 2021[redacted]

Serious Life-Threatening:

Serious Disability:

Serious Hospitalization:

Serious Congenital Anomaly:

Serious Other:

Serious Other Explain:

Reaction 1

Outcome: Died

Reaction Start Date: 2021[redacted]

Reaction End Date:

Reaction Description: 20 hours after the vaccine, developed severe headache"" lightning bolts to brain"", self-treated with advil, 24 hours post-vaccine developed abdominal pain ""like knives to abdomen."" She was in pain and not acting like herself, swearing, said "" give me the damn (advil) bottle, how many of these can I take in a day?"" This headache/abdominal pain continued for a number of days, she then thought she was better and stopped taking the advil and then got way worse. 24 hours before death began feeling like she was going to vomit, vomited for 2 hours and then felt unwell afterwards. Vomit was a reddish colour and she thought it was from ketchup chips, now husband thinks it was not. Anxiety. Clotting leading to death as per her husband. He thinks there were neurological signs before death(mumbling and loss of speech) and that there was a clot in her brain as well. She died before reaching the hospital. Post-mortem COVID test was negative. There was a low platelet count in post-mortem bloodtest, and on autopsy they found lung infarcts and pulmonary embolism as well as a fibroid, the fibroid was pre-existing X 30 years according to husband. no blood clot in brain found on autopsy.

Suspect Product 1

DIN #/NPN #:

Product Name: AstraZeneca COVID-19 vaccine

Strength:

Strength other:

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Dosage form:

Manufacturer: AstraZeneca

Lot #:

Expiry date:

Product start date: 202[redacted]

Product end date:

Dose:

Frequency: this was her first dose of COVID vaccine

Route of administration: Intramuscular

Route of administration - Other:

Indication: infection prevention

Reported to Mfr: No

Date reported to Mfr:

Mfr Reference number:

Drug action taken: Not applicable

Dechallenge: N/A

Rechallenge: N/A

Concomitants: none

Test/Lab results narrative:

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ATIA - 19(1)

Dear [redacted]

Thank you for speaking with representatives, including our Senior Executive Director, Sophie Sommerer, from the Marketed Health Products Directorate of Health Canada on May 11, 13 and 14, 2021, regarding the tragic event that your wife experienced. We would like to extend our deepest sympathy to you and your family for her loss and imagine the pain this matter might bring to you.

The information that you provided via phone and email has been recorded in the Canada Vigilance Program (CVP) database and assigned the Adverse Reaction Report (AER) Number, **000949763**. As requested, please attached documents that present the information that Health Canada used to create this report. Please note that some of the information is not shown in the online submission form due to the sizes of the text. As such, this information is attached in a separate document entitled "supplementary information."

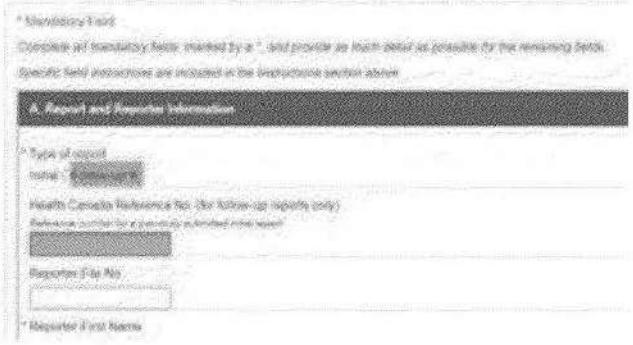
You indicated that you may have additional information on the symptoms your wife experienced. We would invite you to add any additional information that you may have access to, in particular:

- Your wife's height and weight
- The dose and lot number of the vaccine, if known
- Any further information about the symptoms experienced
- Further information from the autopsy or coroner's report if available

In addition, if you find that any of the information included in the report is incorrect, please also indicate that in your follow-up report. For example, "Delete X-incorrect" or "Change Y to Z."

You can provide follow-up information by using the online side effect reporting application. Alternatively, you can email hc.canada.vigilance.sk.sc@canada.ca to let us know the best time and dates to connect with you via phone if you prefer to report verbally.

For online reporting, select the "follow-up" radio button and enter the AER **[000949763]** in the "Health Canada reference no." field as shown below, or notify the coordinator that this a follow-up of the referenced AER number for follow-up by phone.



We greatly appreciate your feedback to ensure that we have the most accurate and comprehensive information.

Thank you again very much for taking the time to speak with us during this difficult time.

Sincerely,

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Canada Vigilance Program
Health Canada, Government of Canada
hc.canada.vigilance.sc@canada.ca / Tel: 1-866-234-2345/ TTY: 1-800-465-7735

Programme Canada Vigilance
Santé Canada, Gouvernement du Canada
hc.canada.vigilance.sc@canada.ca/ Tél. : 1-866-234-2345/ ATS : 1-800-465-7735

Health Canada Santé Canada

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04652541 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220421 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A714773()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210906 CCYYMMDD	20220329 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A714773

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
MC CANADA AZPROD0000	[redacted] CA-AstraZeneca-2021A714773

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female	160 Centimeter	68 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			54 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)	
Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3) Unknown

Patient death cause (B.1.9.2)	
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Aphasia
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Cerebral haemorrhage
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Cerebral venous sinus thrombosis
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Cerebral venous thrombosis
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Cerebrovascular accident
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Coagulopathy
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Confusional state
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Decompressive craniectomy
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Fatigue
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Feeding disorder
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Haemorrhage intracranial
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Headache
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Hyperglycaemia
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Hypertension
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Immune thrombocytopenia
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Intracranial pressure increased
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Muscular weakness
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Nausea
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Neurological decompensation
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Platelet transfusion
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Subarachnoid haemorrhage
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Thrombectomy
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Thrombosis with thrombocytopenia syndrome
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Venous hypertension
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Vision blurred
MedDRA version for cause (B.1.9.2.a) 26.0	Reported cause(s) (B.1.9.2.b) Vomiting

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Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) METFORMIN/SITAGLIPTIN E	
Active Substance names (B.4.k.2.2) METFORMIN SITAGLIPTIN		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	TYLENOL	
Active Substance names (B.4.k.2.2)		
acetaminophen		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL VENOUS THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral venous thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Cerebral venous thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			5 Days
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBROVASCULAR ACCIDENT

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cerebrovascular accident
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COAGULOPATHY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Coagulopathy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Coagulopathy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

IMMUNE THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Immune thrombocytopenia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Immune thrombocytopenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBECTOMY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombectomy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombectomy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VOMITING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vomiting
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vomiting

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DECOMPRESSIVE CRANIECTOMY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Decompressive craniectomy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Decompressive craniectomy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral haemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cerebral haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PLATELET TRANSFUSION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Platelet transfusion		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Platelet transfusion		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VENOUS HYPERTENSION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Venous hypertension		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Venous hypertension		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VISION BLURRED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vision blurred
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Vision blurred

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Headache
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Headache

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Nausea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nausea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Fatigue
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Fatigue

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAEMORRHAGE INTRACRANIAL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Haemorrhage intracranial
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Haemorrhage intracranial

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Thrombosis with thrombocytopenia syndrome			
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Thrombosis with thrombocytopenia syndrome			
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FEEDING DISORDER

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Feeding disorder			
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Feeding disorder			
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL VENOUS SINUS THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Cerebral venous sinus thrombosis			
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Cerebral venous sinus thrombosis			
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

APHASIA

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Aphasia			
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Aphasia			
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CONFUSIONAL STATE

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Confusional state			
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Confusional state			
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Fatal		

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

HYPERTENSION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hypertension		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Hypertension		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HYPERGLYCAEMIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hyperglycaemia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Hyperglycaemia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MUSCULAR WEAKNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Muscular weakness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Muscular weakness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTRACRANIAL PRESSURE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Intracranial pressure increased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Intracranial pressure increased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUBARACHNOID HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Subarachnoid haemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Subarachnoid haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)

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No

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NEUROLOGICAL DECOMPENSATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Neurological decompensation
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Neurological decompensation

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a health professional via the regulatory authority in Canada concerning a female patient of unknown ethnic origin of age 54 years, height 160 cm and weight 68 kg.

No medical history was reported.

Concomitant medication included metformin, sitagliptin and paracetamol.

On an unknown date, the patient received Covid-19 Vaccine Astrazeneca (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number Unknown) once/single administration, via intramuscular route, for covid-19 prophylaxis.

On an unknown date, the patient experienced cerebral venous thrombosis (preferred term: Cerebral venous thrombosis), cerebrovascular accident (preferred term: Cerebrovascular accident), coagulopathy (preferred term: Coagulopathy), immune thrombocytopenia (preferred term: Immune thrombocytopenia), thrombectomy (preferred term: Thrombectomy), vomiting (preferred term: Vomiting), decompressive craniectomy (preferred term: Decompressive craniectomy), cerebral haemorrhage (preferred term: Cerebral haemorrhage), platelet transfusion (preferred term: Platelet transfusion), venous hypertension (preferred term: Venous hypertension), vision blurred (preferred term: Vision blurred), headache (preferred term: Headache), nausea (preferred term: Nausea), fatigue (preferred term: Fatigue), haemorrhage intracranial (preferred term: Haemorrhage intracranial), thrombosis with thrombocytopenia syndrome (preferred term: Thrombosis with thrombocytopenia syndrome), feeding disorder (preferred term: Feeding disorder), cerebral venous sinus thrombosis (preferred term: Cerebral venous sinus thrombosis), aphasia (preferred term: Aphasia), confusional state (preferred term: Confusional state), hypertension (preferred term: Hypertension), hyperglycaemia (preferred term: Hyperglycaemia), muscular weakness (preferred term: Muscular weakness), intracranial pressure increased (preferred term: Intracranial pressure increased), subarachnoid haemorrhage (preferred term: Subarachnoid haemorrhage) and neurological decompensation (preferred term: Neurological decompensation).

It was unknown if any action was taken with Covid-19 Vaccine Astrazeneca.

On an unspecified date, the patient died from the event of cerebral venous thrombosis, cerebrovascular accident, coagulopathy, immune thrombocytopenia, thrombectomy, vomiting, decompressive craniectomy, cerebral haemorrhage, platelet transfusion, venous hypertension, vision blurred, headache, nausea, fatigue, haemorrhage intracranial, thrombosis with thrombocytopenia syndrome, feeding disorder, cerebral venous sinus thrombosis, aphasia, confusional state, hypertension, hyperglycaemia, muscular weakness, intracranial pressure increased, subarachnoid haemorrhage and neurological decompensation.

The cause of death was cerebral venous thrombosis, cerebrovascular accident, coagulopathy, immune thrombocytopenia, thrombectomy, vomiting, decompressive craniectomy, cerebral haemorrhage, platelet transfusion, venous hypertension, vision blurred, headache, nausea, fatigue, haemorrhage intracranial, thrombosis with thrombocytopenia syndrome, feeding disorder, cerebral venous sinus thrombosis, aphasia, confusional state, hypertension, hyperglycaemia, muscular weakness, intracranial pressure increased, subarachnoid haemorrhage and neurological decompensation.

The reporter considered the events of cerebral venous thrombosis, cerebrovascular accident, coagulopathy, immune thrombocytopenia, thrombectomy, vomiting, decompressive craniectomy, cerebral haemorrhage, platelet transfusion, venous hypertension, vision blurred, headache, nausea, fatigue, haemorrhage intracranial, thrombosis with thrombocytopenia syndrome, feeding disorder, cerebral venous sinus thrombosis, aphasia, confusional state, hypertension, hyperglycaemia, muscular weakness, intracranial pressure increased, subarachnoid haemorrhage and neurological decompensation as serious due to seriousness criteria of death.
The reporter considered the events of cerebral venous thrombosis, cerebrovascular accident, immune thrombocytopenia and cerebral haemorrhage were considered serious due to seriousness criteria of important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 vaccine is an AstraZeneca Canada inc product authorized under the interim order.

Summary of follow-up information received by AstraZeneca/MedImmune 29-Mar-2022 from health professional via spontaneous source: New primary reporter health professional added. New events including Haemorrhage intracranial, Thrombosis with thrombocytopenia syndrome, Feeding disorder, Cerebral venous sinus thrombosis, Aphasia,

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Thrombocytopenia syndrome, Feeding disorder, Cerebral venous sinus thrombosis, Aphasia, Confusional state, Hypertension, Hyperglycaemia, Muscular weakness, Intracranial pressure increased, Subarachnoid haemorrhage and Neurological decompensation.

Corrected report on 21-Apr-2022: CCC updated.CAUSE OF DEATH: CEREBRAL VENOUS THROMBOSIS CAUSE OF DEATH: CEREBROVASCULAR ACCIDENT CAUSE OF DEATH: COAGULOPATHY CAUSE OF DEATH: IMMUNE THROMBOCYTOPENIA CAUSE OF DEATH: THROMBECTOMY CAUSE OF DEATH: VOMITING CAUSE OF DEATH: DECOMPRESSIVE CRANIECTOMY CAUSE OF DEATH: CEREBRAL HAEMORRHAGE CAUSE OF DEATH: PLATELET TRANSFUSION CAUSE OF DEATH: VENOUS HYPERTENSION CAUSE OF DEATH: VISION BLURRED CAUSE OF DEATH: HEADACHE CAUSE OF DEATH: NAUSEA CAUSE OF DEATH: FATIGUE CAUSE OF DEATH: HAEMORRHAGE INTRACRANIAL CAUSE OF DEATH: THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME CAUSE OF DEATH: FEEDING DISORDER CAUSE OF DEATH: CEREBRAL VENOUS SINUS THROMBOSIS CAUSE OF DEATH: APHASIA CAUSE OF DEATH: CONFUSIONAL STATE CAUSE OF DEATH: HYPERTENSION CAUSE OF DEATH: HYPERGLYCAEMIA CAUSE OF DEATH: MUSCULAR WEAKNESS CAUSE OF DEATH: INTRACRANIAL PRESSURE INCREASED CAUSE OF DEATH: SUBARACHNOID HAEMORRHAGE CAUSE OF DEATH: NEUROLOGICAL DECOMPENSATION CEREBRAL VENOUS THROMBOSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CEREBROVASCULAR ACCIDENT - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes COAGULOPATHY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes IMMUNE THROMBOCYTOPENIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes THROMBECTOMY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VOMITING - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DECOMPRESSIVE CRANIECTOMY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CEREBRAL HAEMORRHAGE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PLATELET TRANSFUSION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VENOUS HYPERTENSION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VISION BLURRED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HEADACHE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NAUSEA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes FATIGUE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes FEEDING DISORDER - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CEREBRAL VENOUS SINUS THROMBOSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes APHASIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CONFUSIONAL STATE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HYPERTENSION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HYPERGLYCAEMIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MUSCULAR WEAKNESS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes INTRACRANIAL PRESSURE INCREASED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes SUBARACHNOID HAEMORRHAGE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NEUROLOGICAL DECOMPENSATION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NULLIFICATION/AMENDMENT REASON: Amendment: See corrected / amended report paragraph in narrative.
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case concerns a 54-year-old female vaccinee with reported 26 fatal serious adverse events. Thrombosis (PT: Cerebral venous thrombosis, Cerebrovascular accident, Thrombectomy) in combination with thrombocytopenia (PT: Immune thrombocytopenia) is listed in the company core data sheet of AZD1222. However, as the events (PTs: Cerebral venous thrombosis, Cerebrovascular accident, Thrombectomy, Immune thrombocytopenia) were reported with seriousness criteria of death, the combination is considered unlisted. Vomiting, Headache, Nausea and Fatigue are listed in the company core data sheet of AZD1222. However as they were reported with seriousness criteria of death, these events are considered as unlisted. The cause of death reported are all 26 serious events. Concomitant medication metformin and sitagliptin could be considered as confounding factors for Vomiting, Nausea, headache and Fatigue. All the reported events could be in association with each other. Due to limited information on baaseline health condition before vaccination, relevant medical and family history, date of vaccination, event onset and death dates, details and circumstances surrounding the events, possible risk factors (diabetes, cardiovascular disorders, neurological disorders, infection) and detailed diagnostic and etiologic workup (physical examination, neurological findings, complete blood count, blood laboratory tests, coagulation studies, infection profile, electrocardiogram, echocardiogram, chest radiological studies and imaging and abdominal ultrasound/radiological imaging), autopsy report with confirmed final diagnosis, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral venous thrombosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebrovascular accident	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Coagulopathy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Immune thrombocytopenia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombectomy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Vomiting	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Decompressive craniectomy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral haemorrhage	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Platelet transfusion	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Venous hypertension	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Vision blurred	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Headache	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Nausea	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Fatigue	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Haemorrhage intracranial	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Thrombosis with thrombocytopenia syndrome	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Feeding disorder	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Cerebral venous sinus thrombosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Aphasia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Confusional state	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hyperglycaemia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Muscular weakness	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Intracranial pressure increased	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Subarachnoid haemorrhage	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Neurological decompensation	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c): UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2):

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c): UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2):

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a):

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l):

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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SUSPECT ADVERSE REACTION REPORT

CIOMS FORM

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year
68 Kg 160 cm	Canada				54	F	??	??	??

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Cerebral venous thrombosis (10008138) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Cerebrovascular accident (10008190) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Coagulopathy (10009802) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Immune thrombocytopenia (10083842) [v.26.0] - Fatal
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [X] PATIENT DIED
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- [ ] INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [X] OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML(chadox1-s [recombinant])(SOLUTION INTRAMUSCULAR)(chadox1-s [recombinant]),Unknown

Cont...

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
Dose Unknown ONCE/SINGLE

16. ROUTE(S) OF ADMINISTRATION
Intramuscular

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATION(S) FOR USE
COVID-19 prophylaxis[10084458] [v.26.0]

18. THERAPY DATES(from/to)

19. THERAPY DURATION

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

METFORMIN/SITAGLIPTIN E(METFORMIN, SITAGLIPTIN)(METFORMIN, SITAGLIPTIN) — ONCE/SINGLE ADMINISTRATION

Cont...

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
HealthCanada_Post_Market
Canada

24b. MFR. CONTROL NO.
CA-AstraZeneca-2021A714773
Log No : 2021A714773

24c. DATE RECEIVED BY MANUFACTURER
21/APR/2022

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
21/APR/2022

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP

COVID-19 VACCINE ASTRAZENECA
COVID-19 VACCINE ASTRAZENECA
COVID-19 VACCINE ASTRAZENECA

Company Remarks (Sender's comments) :
This case concerns a 54-year-old female vaccinee with reported 26 fatal serious adverse events. Thrombosis (PT: Cerebral venous thrombosis, Cerebrovascular accident, Thrombectomy) in combination with thrombocytopenia (PT: Immune thrombocytopenia) is listed in the company core data sheet of AZD1222. However, as the events (PTs: Cerebral venous thrombosis, Cerebrovascular accident, Thrombectomy, Immune thrombocytopenia) were reported with seriousness criteria of death, the combination is considered unlisted. Vomiting, Headache, Nausea and Fatigue are listed in the

Cont...

Cont... = Continuation attached sheet(s)

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A714773**

Reaction Information (Cont...)

Seq. No. : 1
Reaction : Cerebral venous thrombosis (10008138) [v.26.0]
Duration : 5 D

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Thrombectomy (10043530) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Vomiting (10047700) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Decompressive craniectomy (10078092) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Cerebral haemorrhage (10008111) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Platelet transfusion (10035543) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Venous hypertension (10082503) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Vision blurred (10047513) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Headache (10019211) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Nausea (10028813) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Fatigue (10016256) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Haemorrhage intracranial (10018985) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Thrombosis with thrombocytopenia syndrome (10086158) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Feeding disorder (10061148) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Cerebral venous sinus thrombosis (10083037) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Aphasia (10002948) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Confusional state (10010305) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A714773**

Hypertension (10020772) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Hyperglycaemia (10020635) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Muscular weakness (10028372) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Intracranial pressure increased (10022773) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Subarachnoid haemorrhage (10042316) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Neurological decompensation (10068357) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Fatal

A spontaneous report has been received from a health professional via the regulatory authority in Canada concerning a female patient of unknown ethnic origin of age 54 years, height 160 cm and weight 68 kg.

No medical history was reported.

Concomitant medication included metformin, sitagliptin and paracetamol.

On an unknown date, the patient received Covid-19 Vaccine Astrazeneca (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number Unknown) once/single administration, via intramuscular route, for covid-19 prophylaxis.

On an unknown date, the patient experienced cerebral venous thrombosis (preferred term: Cerebral venous thrombosis), cerebrovascular accident (preferred term: Cerebrovascular accident), coagulopathy (preferred term: Coagulopathy), immune thrombocytopenia (preferred term: Immune thrombocytopenia), thrombectomy (preferred term: Thrombectomy), vomiting (preferred term: Vomiting), decompressive craniectomy (preferred term: Decompressive craniectomy), cerebral haemorrhage (preferred term: Cerebral haemorrhage), platelet transfusion (preferred term: Platelet transfusion), venous hypertension (preferred term: Venous hypertension), vision blurred (preferred term: Vision blurred), headache (preferred term: Headache), nausea (preferred term: Nausea), fatigue (preferred term: Fatigue), haemorrhage intracranial (preferred term: Haemorrhage intracranial), thrombosis with thrombocytopenia syndrome (preferred term: Thrombosis with thrombocytopenia syndrome), feeding disorder (preferred term: Feeding disorder), cerebral venous sinus thrombosis (preferred term: Cerebral venous sinus thrombosis), aphasia (preferred term: Aphasia), confusional state (preferred term: Confusional state), hypertension (preferred term: Hypertension), hyperglycaemia (preferred term: Hyperglycaemia), muscular weakness (preferred term: Muscular weakness), intracranial pressure increased (preferred term: Intracranial pressure increased), subarachnoid haemorrhage (preferred term: Subarachnoid haemorrhage) and neurological decompensation (preferred term: Neurological decompensation).

It was unknown if any action was taken with Covid-19 Vaccine Astrazeneca.

On an unspecified date, the patient died from the event of cerebral venous thrombosis, cerebrovascular accident, coagulopathy, immune thrombocytopenia, thrombectomy, vomiting, decompressive craniectomy, cerebral haemorrhage, platelet transfusion, venous hypertension, vision blurred, headache, nausea, fatigue, haemorrhage intracranial, thrombosis with thrombocytopenia syndrome, feeding disorder, cerebral venous sinus thrombosis, aphasia, confusional state, hypertension, hyperglycaemia, muscular weakness, intracranial pressure increased, subarachnoid haemorrhage and neurological decompensation.

The cause of death was cerebral venous thrombosis, cerebrovascular accident, coagulopathy, immune thrombocytopenia, thrombectomy, vomiting, decompressive craniectomy, cerebral haemorrhage, platelet transfusion, venous hypertension, vision blurred, headache, nausea, fatigue, haemorrhage intracranial, thrombosis with thrombocytopenia syndrome, feeding disorder, cerebral venous sinus thrombosis, aphasia, confusional state, hypertension, hyperglycaemia, muscular weakness, intracranial pressure increased, subarachnoid haemorrhage and neurological decompensation.

The reporter considered the events of cerebral venous thrombosis, cerebrovascular accident, coagulopathy, immune thrombocytopenia, thrombectomy, vomiting, decompressive craniectomy, cerebral haemorrhage, platelet transfusion, venous hypertension, vision blurred, headache, nausea, fatigue, haemorrhage intracranial, thrombosis with thrombocytopenia syndrome, feeding disorder, cerebral venous sinus thrombosis, aphasia, confusional state, hypertension, hyperglycaemia, muscular weakness, intracranial pressure increased, subarachnoid haemorrhage and neurological decompensation as serious due to seriousness criteria of death. The reporter considered the events of cerebral venous thrombosis, cerebrovascular accident, immune thrombocytopenia and cerebral haemorrhage were considered serious due to seriousness criteria of important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A714773**

The Astra-Zeneca COVID-19 vaccine is an AstraZeneca Canada inc product authorized under the interim order.

Summary of follow-up information received by AstraZeneca/MedImmune 29-Mar-2022 from health professional via spontaneous source: New primary reporter health professional added. New events including Haemorrhage intracranial, Thrombosis with thrombocytopenia syndrome, Feeding disorder, Cerebral venous sinus thrombosis, Aphasia, Confusional state, Hypertension, Hyperglycaemia, Muscular weakness, Intracranial pressure increased, Subarachnoid haemorrhage and Neurological decompensation.

Corrected report on 21-Apr-2022: CCC updated.CAUSE OF DEATH: CEREBRAL VENOUS THROMBOSIS CAUSE OF DEATH: CEREBROVASCULAR ACCIDENT CAUSE OF DEATH: COAGULOPATHY CAUSE OF DEATH: IMMUNE THROMBOCYTOPENIA CAUSE OF DEATH: THROMBECTOMY CAUSE OF DEATH: VOMITING CAUSE OF DEATH: DECOMPRESSIVE CRANIECTOMY CAUSE OF DEATH: CEREBRAL HAEMORRHAGE CAUSE OF DEATH: PLATELET TRANSFUSION CAUSE OF DEATH: VENOUS HYPERTENSION CAUSE OF DEATH: VISION BLURRED CAUSE OF DEATH: HEADACHE CAUSE OF DEATH: NAUSEA CAUSE OF DEATH: FATIGUE CAUSE OF DEATH: HAEMORRHAGE INTRACRANIAL CAUSE OF DEATH: THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME CAUSE OF DEATH: FEEDING DISORDER CAUSE OF DEATH: CEREBRAL VENOUS SINUS THROMBOSIS CAUSE OF DEATH: APHASIA CAUSE OF DEATH: CONFUSIONAL STATE CAUSE OF DEATH: HYPERTENSION CAUSE OF DEATH: HYPERGLYCAEMIA CAUSE OF DEATH: MUSCULAR WEAKNESS CAUSE OF DEATH: INTRACRANIAL PRESSURE INCREASED CAUSE OF DEATH: SUBARACHNOID HAEMORRHAGE CAUSE OF DEATH: NEUROLOGICAL DECOMPENSATION CEREBRAL VENOUS THROMBOSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CEREBROVASCULAR ACCIDENT - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes COAGULOPATHY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes IMMUNE THROMBOCYTOPENIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes THROMBECTOMY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VOMITING - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DECOMPRESSIVE CRANIECTOMY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CEREBRAL HAEMORRHAGE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PLATELET TRANSFUSION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VENOUS HYPERTENSION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VISION BLURRED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HEADACHE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NAUSEA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes FATIGUE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes FEEDING DISORDER - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CEREBRAL VENOUS SINUS THROMBOSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes APHASIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CONFUSIONAL STATE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HYPERTENSION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HYPERGLYCAEMIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MUSCULAR WEAKNESS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes INTRACRANIAL PRESSURE INCREASED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes SUBARACHNOID HAEMORRHAGE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NEUROLOGICAL DECOMPENSATION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NULLIFICATION/AMENDMENT REASON: Amendment: See corrected / amended report paragraph in narrative.
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Company Remarks (Sender's comments) (Cont...)

company core data sheet of AZD1222. However as they were reported with seriousness criteria of death, these events are considered as unlisted. The cause of death reported are all 26 serious events. Concomitant medication metformin and sitagliptin could be considered as confounding factors for Vomiting, Nausea, headache and Fatigue. All the reported events could be in association with each other. Due to limited information on baseline health condition before vaccination, relevant medical and family history, date of vaccination, event onset and death dates, details and circumstances surrounding the events, possible risk factors (diabetes, cardiovascular disorders, neurological disorders, infection) and detailed diagnostic and etiologic workup (physical examination, neurological findings, complete blood count, blood laboratory tests, coagulation studies, infection profile, electrocardiogram, echocardiogram, chest radiological studies and imaging and abdominal ultrasound/radiological imaging), autopsy report with confirmed final diagnosis, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No. : 1
Drug : VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML(chadox1-s [recombinant])(SOLUTION INTRAMUSCULAR)(chadox1-s [recombinant]),Unknown
Daily Dose : 1) Dose Unknown ONCE/SINGLE ADMINISTRATION
Route of Admin : 1) Intramuscular

Causality

1) Cerebral venous thrombosis (10008138) [v.26.0]
Action(s) taken with drug : Unknown

Concomitant drugs (Cont...)

Seq.No. : 1
Drug : METFORMIN/SITAGLIPTIN E(METFORMIN, SITAGLIPTIN)(METFORMIN, SITAGLIPTIN)
Route of Admin : 1) Unknown

Seq.No. : 2
Drug : TYLENOL(acetaminophen)(NOT SPECIFIED)(acetaminophen)
Daily Dose : 1) ONCE/SINGLE ADMINISTRATION
Route of Admin : 1) Unknown

Initial Reporter (Cont...)

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A714773**

PRIVACY UNKNOWN PRIVACY
UNKNOWN
UNKNOWN, UNKNOWN UNKNOWN
Canada

DRAFT

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Canada Vigilance AER#:	E2B_04677486 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211112 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101191323(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210909 CCYYMMDD	20211108 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2) CA-PFIZER INC-202101191323

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101191323

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04841533

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			19 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04677486 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED THE NEXT MORNING AFTER GETTING THE VACCINE AFTER JOGGING.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer. A 19-year-old female patient received BNT162B2, via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose number unknown, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient died the next morning after getting the vaccine after jogging on an unspecified date. Caller stated the vaccine is causing death, permanent disability, blindness, heart attacks, strokes, and blood clots being the number 1 thing. The patient died on an unspecified date. It was unknown if an autopsy was performed. The outcome of the event was fatal.

The following information on the lot/batch number has been requested.

Follow-up (08Nov2020): This follow-up is being submitted to notify that the batch/lot number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04677486 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04681454 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210917 CCYYMMDD
	HC Initial Received Date:	20210917 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101197454(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210913 CCYYMMDD	20210913 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101197454

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101197454

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			16 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04681454 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 5 Days	**Last period (B.4.k.13.2)** 5 Days	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
5 Days	5 Days	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from the Pfizer Sponsored Program Pfizer.com - General Company Information, received from a contactable consumer. A 16-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient died five days after he took the vaccine. The outcome of the event was fatal. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04689995 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210921 CCYYMMDD	
	HC Initial Received Date: 20210921 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-319893(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210913 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20210913 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) Yes		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2021-319893

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) irms QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-irms-MDCA21-03016 CA-MODERNATX, INC.-MOD-2021-319893

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_04689993, (2) E2B_04690139

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 19 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

19 YEAR OLD WOMAN GOT THE MODERNA VACCINE IN AND DIED THE NEXT DAY.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of DEATH (19 year old woman got the Moderna vaccine in and died the next day.) in a 19-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

No relevant concomitant and treatment medications were reported.

This case concerns a 19 year-old female patient with no details on past medical history, with unexpected events reported of Death which was happed one day after the administration of Moderna Vaccine (date of vaccination not reported including the dose number). The reported cause is unknown including if an autopsy was done. The benefit risk relationship of Moderna vaccine is not affected by this report.

This case was linked to MOD-2021-319899 (Patient Link).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case concerns a 19 year-old female patient with no details on past medical history, with unexpected events reported of Death which was happed one day after the administration of Moderna Vaccine (date of vaccination not reported including the dose number). The reported cause is unknown including if an autopsy was done. The benefit risk relationship of Moderna vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04738411 (3)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211102 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101275114(4)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	Yes
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-PFIZER INC-202101275114

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Pfizer PFIZERINC	202101294913 CA-PFIZER INC-202101275114

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			35 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Kidney failure
26.0	Liver failure
26.0	Liver inflammation

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	F 7206	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)	
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**
26.0	Amenorrhea

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Amenorrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coloring yellow	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coloring yellow	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hepatomegaly	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hepatomegaly	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Kidney failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Kidney failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Liver failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Liver failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Liver inflammation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Liver inflammation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oedematous weight gain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oedematous weight gain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swelling of legs	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swelling of legs	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Unable to walk	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unable to walk	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	UTI	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	UTI	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	White blood cell count increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	White blood cell count increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Yellow ocular coloring	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Yellow ocular coloring	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HER LIVER HAD DOUBLED IN SIZE DUE TO INFLAMMATION IN SUCH A SHORT TIME

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Liver inflammation		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hepatitis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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HER KIDNEY FAILING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Kidney failure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Renal failure		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LIVER FAILURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Liver failure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hepatic failure		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHE STARTED TO EXPERIENCE JAUNDICE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Jaundice		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Jaundice		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
25 Days	25 Days	Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHE MISSED HER PERIOD 6-7 WEEKS POST-VACCINATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Amenorrhea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Amenorrhoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
23 Days	23 Days	Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HER LEGS WERE VERY SWOLLEN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Swelling of legs		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Peripheral swelling		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHE CAN'T EVEN WALK.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unable to walk
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Gait inability

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UTI

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	UTI
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Urinary tract infection

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LIVER WENT FROM THE SIZE OF A BASEBALL TO THE SIZE OF A FOOTBALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Hepatomegaly
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Hepatomegaly

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHE WENT INTO THE HOSPITAL AT 130 POUNDS (LBS), SHE'S NOW 160-165LBS.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Oedematous weight gain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oedema

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HER EYES AND SKIN TURNED YELLOW

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Yellow ocular coloring
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**

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26.0	Ocular icterus		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HER EYES AND SKIN TURNED YELLOW

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Coloring yellow		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Yellow skin		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNBALANCED BLOOD WORK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Blood test abnormal		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Blood test abnormal		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WHITE BLOOD CELL COUNT WAS VERY HIGH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	White blood cell count increased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	White blood cell count increased		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FIRST DOSE ON [redacted]2021 AND THE SECOND DOSE ON [redacted]2021

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Inappropriate schedule of vaccine administered		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Inappropriate schedule of product administration		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 202[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Headache
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Headache

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Weakness
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Asthenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (patient's husband). A 35-year-old female patient received BNT162B2 (COMIRNATY, lot number F 7206 (missing letter, reporter will try to find the complete lot number)), via an unspecified route of administration on [redacted]2021 (at the age of 35-year-old) as dose 2, single for COVID-19 immunisation. The patient's medical history was reported as no prior conditions or low immune system. It was also reported that the patient was healthy and lived a regular life. Concomitant medications were not reported. The patient received the first dose of COMIRNATY (lot number: EW0221) on [redacted]021 (at the age of 35-year-old) for COVID-19 Immunization and experienced mild symptoms (headache and weakness). The reporter stated that on [redacted]2021, the patient missed her period 6-7 weeks post-vaccination which in the 14 years he's known her had never happened. On [redacted]2021 the patient started to experience jaundice. Her eyes and skin turned yellow. Her legs were very swollen. It felt like she was hit by a truck. She went to her Dr. for some blood tests. Her white blood cell count was very high, she developed a UTI (urinary tract infection), her liver was inflamed and her kidney failing in 2021. Her liver had doubled in size due to inflammation in such a short time, clarifying her liver went from the size of a baseball to the size of a football in 2021. She was treated as an alcoholic, but she kept telling them she was not an alcoholic. She may occasionally have wine on the weekends. Her doctors said that her liver was inflamed, and she had been given steroids, but nothing happened she wasn't responding to steroid therapy. She went into the hospital at 130lbs, she's now 160-165lbs in 2021. Reporter's wife was dying in the hospital. She was waiting to get a liver transplant. Her legs were inflamed and she could not even walk. She was admitted to the hospital in 2021 and was now in hospice care, she was not expected to make a recovery and will die according to the doctors. As per her husband, her kidney had failed and her liver was "fried". The husband wanted to know if there had been other reports of liver failure after receiving the vaccine. The doctors said she only had hours to days to live and putting her in palliative care. The doctor did not ask if she had a low immune system prior, and if she did, he would've recommended only getting one dose of the COVID vaccine. She used to run a kilometer a day, run his business. He didn't know how her liver could be fried after being so healthy. As of [redacted]021, it was reported that the patient passed away. Event unbalanced blood work (unspecified date) that was done at her physician's office required hospitalization. Yellow eyes required physician visit. Reporter stated that when the patient woke up one morning with yellow eyes, he took her to his family physician that prescribed blood work. The results were very alarming. His family physician sent her family physician a request to see patient urgently. Her family physician only saw her 2 weeks later and sent her to the Emergency Room (ER) right away. Reporter will be sending lab work and hospital summary. The outcome of events her liver had doubled in size due to inflammation in such a short time, her kidney failing, liver failure was fatal, outcome of events unbalanced blood work was unknown, the outcome of the other events was not recovered. The patient died on an unspecified date in 2021. It was unknown if an autopsy was performed.

The lot number for BNT162b2 was not provided and will be requested during follow up.

Follow-up [redacted]021): New information from the same contactable consumer includes: suspect vaccination details (second dose reported as suspect), first vaccine dose details, medical history, events clinical course details, lab data.

Follow-up [redacted]021): This is a follow-up report combining information from duplicate reports 202101294913 and 202101275114. The current and all subsequent follow-up information will be reported under manufacturer report number 202101275114. The new information reported from a patient's husband includes new events "Liver failure" and "She went into the hospital at 130 pounds (lbs), she's now 160-165lbs." added and event details (outcome, onset date for event "She missed her period 6-7 weeks post-vaccination").

Follow-up [redacted]021): New information received from the same contactable consumer (patient's husband) includes: patient data (death information and lab data added, historical vaccine date updated), event data (new event unbalanced blood work added), and clinical details.

Follow-up attempts are completed. No further information is expected.

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021 CCYY	Blood test	Her white blood cell count was very high	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021 CCYY	Weight	160-165	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
lbs			Yes

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021 CCYY	White blood cells	very high	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood test	Unbalanced	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Weight	130	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
lbs			Yes

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Weight	58.957	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
kg			No

Results of tests and procedures (B.3.2)

Weight([redacted]2021):She's now 160-165lbs.
Blood test():The results were very alarming.
Blood test([redacted]2021):she developed a UTI (urinary tract infection) infection, her liver was inflamed and her kidney failing
Weight():went into the hospital

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Liver inflammation	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Kidney failure	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Liver failure

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

List of non-encoded Patient Relevant History:
Patient Other Relevant History 1: none

Past drug therapy (B.1.8)

Drug name (B.1.8a)

BNT162B2

Start date (B.1.8c)	End date (B.1.8e)
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	COVID-19 immunization
26.0	COVID-19 immunization

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)
v.26.0	Headache
v.26.0	Weakness

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211007 CCYYMMDD	
	HC Initial Received Date: 20211007 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101275355(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101275355

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101275355

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021 CCYY	2021 CCYY	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sickness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Sickness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAST AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SICK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Sickness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Illness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (patient's wife friend). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number was not reported), via an unspecified route of administration on an unspecified date in 2021 as dose 2, single for covid-19 immunsation. The patient's medical history and concomitant medications were not reported. The reporter complained that how there was no informing "a lot of people died from the Pfizer Covid Vaccine. They were not getting the materials safety data sheet. It's a lie. A lot of people have died. They died, millions of them died from the Covid vaccine. It will cause infertility, cancer and ultimately death. It's not saving lives, it's making people sick. In line with this, the reporter's friend just called and told the reporter that the friend's husband past away 2 weeks ago [redacted]021). The patient got sick from his 2nd dose of Pfizer COVID-19 Vaccine, and he died. The patient got the vaccine 2 or 3 months ago. The patient died in [redacted]021. Cause of death was unknown. The outcome of sick was unknown; outcome of past away was fatal. It was unknown if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210527 CCYYMMDD
	HC Initial Received Date:	20210527 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR_H-20210527115449_30179()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021 CCYY	2021 CCYY	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) 000977087

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital - [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Female	160 Centimeter	68 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			54 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

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Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	MT0056	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
frequencytext:Inject first dose at once		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	202[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
9 Days	9 Days	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) METFORMIN/SITAGLIPTINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TYLENOL	
Active Substance names (B.4.k.2.2) acetaminophen		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL SINUS VENOUS THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Cerebral venous thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Cerebral venous thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 202[redacted] CCYYMMDD	End Date (B.2.i.5) 202[redacted] CCYYMMDD	Duration (B.2.i.6) 5 Days
Reaction first time (B.2.i.7.1) 9 Days	Reaction last time (B.2.i.7.2) 9 Days	Outcome (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUSPECTED VIPIT VACCINE INDUCED PROTHROMBOTIC IMMUNE THROMBOCYTOPENIA

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Immune thrombocytopenia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Immune thrombocytopenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VENOUS HYPERTENSION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Venous hypertension
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Venous hypertension

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VENOUS THROMBECTOMY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombectomy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombectomy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LARGE LEFT HEMISPHERIC HEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cerebral hemorrhage
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebral haemorrhage

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PLATELET TRANSFUSION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Platelet transfusion
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Platelet transfusion

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
1 Days	1 Days		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fatigue		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fatigue		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nausea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Nausea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
5 Days	5 Days		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VOMITING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Vomiting		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Vomiting		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLURRED VISION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Blurred vision
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vision blurred

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BILATERAL DECOMPRESSIVE CRANIECTOMY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Decompressive craniectomy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Decompressive craniectomy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CAUSED AVC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	CVA
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COAGULOPATHY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Coagulopathy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Coagulopathy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Summary (B.5)

Case narrative (B.5.1)

Patient received 1st dose of AstraZeneca Vaccine o[redacted], then started having headache and fatigue on[redacted] The symptoms worsened over the following days and on[redacted] she started having nausea, vomiting and blurred vision. She went to ER on[redacted] and was quickly transferred to[redacted] on[redacted] due to a cerebral sinus venous thrombosis secondary to suspected VIPIT (Vaccine Induced Prothrombotic Immune Thrombocytopenia). Patient was started on IVIG and Argatroban. She deteriorated neurologically presumably due to venous hypertension and was started on hypertonic medication and underwent a venous thrombectomy. Patient transiently improved post procedure but unfortunately had a large left hemispheric hemorrhage in the context of severe thrombocytopenia (9000) + Argatroban. She received platelet transfusion urgently and underwent a bilateral decompressive craniectomy on[redacted] Unfortunately, she did not improve neurologically after this and after discussion with her family, life supportive measures were withdrawn and patient passed away shortly after on[redacted]

Dhpr log details:
Safety Report ID: CA-DHPR_H-20210527115449_30179
Type of Report: Initial
HC Ref. No:
Reporter File No.:[redacted]
Transmission Date: 20210527
Documentation Date: 202[redacted]
First Name:[redacted]
Last Name:[redacted]
Telephone:[redacted]

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Ext.: [redacted]
Address:
City:
Province/Territory:
Postal Code:
Email address: [redacted]
Organization:
HC ID [redacted]
Reporter Type: Pharmacist

Patient ID: [redacted]
Age: 54 Year(s)
Sex: Female
Height: 160 cm
Weight: 68 kg
Med History: Diabetes
History of nephrectomy
Allergies: Amoxicillin: pan corporal rash per patient
Nuts (except almonds)
Apple: fresh apples only, can eat if well washed/peeled/cooked.

Serious Death: Yes
Date of Death: 202[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Died
Reaction Start Date: 2021[redacted]
Reaction End Date: 202[redacted]
Reaction Description: Severe and multiple cerebral sinus venous thrombosis secondary to VIPIT (see additional description below), caused AVC and bleeding due to coagulopathy/severe thrombocytopenia (platelet < 10 000)

Suspect Product 1
DIN #/NPN #: 02510847
UPHN #:
Brand Name: AstraZeneca COVID-19 Vaccine
Common Name: ChAdOx1-S* recombinant
Strength: 50000000 Other (describe)
Strength other: 50000000000 VP / 0.5 ML
Dosage form: solution
Manufacturer: AstraZeneca
Lot #: MT0056
Expiry date:
Product start date: 2021[redacted]
Product end date: 202[redacted]
Dosage:
Dosage other:
Frequency: Inject first dose at once
Route of administration: Intramuscular
Route of administration - Other:
Indication: Prevention of COVID-19
Reported to Mfr: No
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Not applicable
Dechallenge: Unknown
Rechallenge: Unknown

Concomitants: Metformin + sitagliptin 1000-50mg PO BID
OTC - Tylenol PRN (dose unknow)
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Nephrectomy	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug allergy	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Allergy to nuts	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Food allergy	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Diabetes
History of nephrectomy
Allergies:Amoxicillin: pan corporal rash per patient
Nuts (except almonds)
Apple: fresh apples only, can eat if well washed/peeled/cooked.

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) [redacted]	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) [redacted]
Reporter organization (A.2.1.2a) [redacted]		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) [redacted]			
Reporter city (A.2.1.2d) [redacted]		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f) [redacted]	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Pharmacist
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220120 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101359925(5)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 202[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220110 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	Yes
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-202101359925

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-202101359925

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04767142, (2) E2B_04767142, (2) E2B_04767142, (2) E2B_04767142, (2) E2B_04767142, (2) E2B_04767142, (2) E2B_04767142, (2) E2B_04767142

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1) 7 Weeks		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Congenital anomaly
26.0	Spontaneous abortion

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	FD7206	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.3 ml 1 (Total)		
Dosage text (B.4.k.6)		
DOSE 1, 0.3 ML SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Transplacental	Intramuscular
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
5 Weeks	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
18590 Minutes	18590 Minutes	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
ExpDT=30-NOV-2021		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)	
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**
26.0	Congenital anomaly

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Congenital anomaly	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Spontaneous abortion	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Spontaneous abortion	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** BIOTIN/CALCIUM CARBONATE/CALCIUM D-PANTOTHENATE/CHROMIUM NICOTINATE/CUPRIC OXIDE/D-ALPHA TOCOPHERYL ACETATE/FERROUS FUMARATE/FOLIC ACID/MAGNESIUM HYDROXIDE/MANGANESE GLUCONATE/NICOTINAMIDE/POTASSIUM IODIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN	
Active Substance names (B.4.k.2.2) ascorbic acid selenomethionine ferrous fumarate vitamin k1 biotin calcium d-pantothenate pyridoxine hydrochloride nicotinamide thiamine hydrochloride cupric oxide manganese gluconate magnesium hydroxide calcium carbonate riboflavin potassium iodide zinc gluconate sodium molybdate vitamin a cyanocobalamin d-alpha tocopheryl acetate chromium nicotinate vitamin d3 folic acid		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Transplacental	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CONGENITAL ANOMALY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Congenital anomaly		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Congenital anomaly		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
18590 Minutes	18590 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

AT THE TIME OF MY INJECTION I WAS 5 WEEKS PREGNANT.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Maternal exposure during pregnancy, first trimester		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Maternal exposure during pregnancy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
18590 Minutes	18590 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SPONTANEOUS ABORTION/ MISCARRIAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Spontaneous abortion		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Abortion spontaneous		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
17870 Minutes	17870 Minutes	Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received via COVAES from a contactable consumer professional (baby's mom). This consumer reported for both the mother and baby case. This is the baby case.

A fetus patient of an unspecified gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 transplacental on [redacted]2021 14:10 (Lot Number: FD7206; expiration date: 30Nov2021) as dose 1, 0.3 ml single for COVID-19 immunization. The mother at 32-years-old received the vaccine via intramuscular on [redacted]2021 in the Arm Right. The last menstrual period [redacted]2021 pregnancy due date is on [redacted]2022. The mother also did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No history of pregnancy complications, bleeding, spotting, and no history of miscarriage. 4 healthy, successful pregnancies. The patient medical history was not reported. Concomitant medication included ascorbic acid, biotin, calcium carbonate, calcium pantothenate, chromium nicotinate, colecalciferol, cupric oxide, cyanocobalamin, ferrous fumarate, folic acid, magnesium hydroxide, manganese gluconate, nicotinamide, phytomenadione, potassium iodide, pyridoxine hydrochloride, retinol, riboflavin, selenomethionine, sodium molybdate, thiamine hydrochloride, tocopheryl acetate, zinc gluconate (MULTIVITAMIN FOR WOMEN) taken for an unspecified indication, start and stop date were not reported. It was reported that the patient experienced Congenital anomaly/birth defect (reported as Congenital anomaly/birth defect: YES). The mother reported that: "At the time of my injection I was 5 weeks pregnant. I miscarried 13 days later (also reported a[redacted]2021 12:00). It was reported patient experienced Spontaneous abortion/ miscarriage with onset [redacted]2021 (Medically significant), outcome "fatal". I have no history of pregnancy complications, bleeding, spotting, and no history of miscarriage. I have had 4 healthy, successful pregnancies. I have no reason to believe this pregnancy would have been any different if not for receiving this vaccine which doesn't have adequate testing on pregnant women" The patient died on [redacted]2021. The reported cause of death was congenital anomaly and abortion spontaneous. It was not reported if an autopsy was performed. The events resulted in Doctor or other healthcare professional office/clinic visit. Outcome of previous pregnancies: live births- no complications. No problems before, after and during delivery. Mother and father did not smoke, drink alcohol, ilicit during this pregnancy.

This follow-up report is being submitted to amend previously reported information: Amendment: narrative updated to reflect that the events resulted in Doctor or other healthcare professional office/clinic visit.

According to the Product Quality Complaint Group report received on [redacted]2021: The investigation included reviewing the involved batch records, deviation investigation and an analysis of the complaint history for the reported lot and product type. The final scope was determined to be the associated lot(s) of the reported lot FD7206. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation and stability. PGS Puurs concludes that the reported defect is not representative of the quality of the batch and the batch remains acceptable. The NTM process determined that no regulatory notification was required. The reported defect could not be confirmed. No root cause or CAPA were identified as the complaint was not confirmed.

Follow-up ([redacted]2021): New information included Investigational report conclusion from Kalamazoo (EP) division for dose 1 (lot number: FD7206; expiration date: 30Nov2021).

Follow up ([redacted]021): This is a spontaneous follow-up report received from the same contactable consumer. Updated information included: Parent Route of Administration

Follow-up [redacted]2021): Follow-up attempts completed. No further information is expected

Follow up(10Jan2022): New information received via fax from a contactable reporter (Physician) Updated information: New adverse event Spontaneous abortion was added. New reporter added. Time for 1st dose was updated (BNT162B2). Biological Product box updated. Correspondence contact added. Patient tab was updated. Narrative updated. Clinical course information added.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

As there is limited information in the case provided, the causal association between the event abortion spontaneous with the suspect drug BNT162B2 cannot be excluded. The case will be reassessed once new information is available.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Spontaneous abortion	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	Episode name (B.1.7.1a.2) Congenital anomaly	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211015 CCYYMMDD
	HC Initial Received Date:	20211015 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101366806(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211012 CCYYMMDD	20211012 CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101366806

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101366806

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			86 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Hemoglobin low

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMM	202[redacted] CCYYMM	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Hemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW HEMOGLOBIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hemoglobin low		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Haemoglobin decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DOSE 1 [redacted]21, DOSE 2 [redacted]21

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Inappropriate schedule of vaccine administered		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Inappropriate schedule of product administration		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received via COVAES from a non-contactable consumer (patient). An 86-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE mRNA Vaccine), dose 2 via an unspecified route of administration on [redacted]2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. There was no concomitant medication. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced low hemoglobin on [redacted]2021 requiring transfusion of blood, hospitalization and then more blood and then death. Duration of hospitalization was 11 days. The event was serious as death, hospitalization, medically significant, life threatening. The event result in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. The patient died in [redacted]2021. It was not reported if an autopsy was performed. Since the vaccination, the patient had not been tested for COVID-19.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
2021[redacted] CCYYMM	Hemoglobin	Low

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemoglobin low	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)
BNT162B2

Start date (B.1.8c)	End date (B.1.8e)
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
26.0	COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04783451 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211209 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

US-PFIZER INC-202101368364(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20211013 CCYYMMDD	20211125 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) US-PFIZER INC-202101368364

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Pfizer	US-PFIZER INC-202101368474
Pfizer	US-PFIZER INC-202101368837
Pfizer	US-PFIZER INC-202101368474
PFIZERINC	US-PFIZER INC-202101368364

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			76 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04783451 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

ATIA - 19(1)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 14 Days	**Last period (B.4.k.13.2)** 14 Days	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Clot blood	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Clot blood	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Liver disorder	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Liver disorder	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04783451 (2)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
14 Days	14 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LIVER STARTED TO GO DOWNHILL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Liver disorder		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Liver disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from contactable consumers via medical information team. A 76-year-old (reported as 75-78 years, pending clarification) female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on [redacted]2021 (Batch/Lot number was not reported) as single for COVID-19 immunization. Medical history included diabetes, renal failure: She was doing in-home care on renal dialysis, and heart attack from Aug2020 (pending clarification). The patient had a heart attack and was pretty stressed out from all the lock downs, she ended up getting 4 stents, was gifted with dialysis and renal failure as a result. She was doing in-home hospice care on renal dialysis. The patient's concomitant medications were not reported. The patient received the Pfizer Covid 19 vaccine on [redacted]2021. On [redacted]2021, she developed a blood clot in her leg. On [redacted]021, her affected leg was amputated. Her health started to deteriorate rapidly, whatever was spreading in her body went to her other leg so the surgeon wanted to remove the other leg but was afraid she wouldn't get past the anesthesia part and wouldn't come back. The surgeon felt like she would not be able to pull through the surgery. The reporter believed that her liver started to go downhill (2021). The patient passed away in [redacted]2021. The reporter added that he knew people would try to say she had preexisting conditions, she was under a lot of stress, but she didn't need to lose her leg and she didn't need to die as a result of this. The reporter mentioned that his partner's aunt received COMIRNATY on [redacted]021 in Canada. Two weeks later (on [redacted]2021), she had a blood clot, and on [redacted]2021 (the 15th day), she lost her leg, got worse, then passed away in [redacted]021. The patient died on [redacted]2021. It was not reported if an autopsy was performed.

The events occurred in a country different from that of the reporter. This may be a duplicate report if another reporter from the country where the event occurred has submitted the same information to his/her local agency.

The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.

Follow-up (25Oct2021): This is a follow-up report combining information from duplicate reports 202101368474 and 202101368364. The current and all subsequent information will be reported under manufacturer report number 202101368364.

The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.

Follow-up (25Nov2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
202008 CCYYMM		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Renal failure	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
202008 CCYYMM		
Comments (B.1.7.1g)		
She was doing in-home care on renal dialysis		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
202008 CCYYMM		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Coronary stent placement	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dialysis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Stress	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) United States of America	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_04783451 (2)	Page#7

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04790127 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211019 CCYYMMDD
	HC Initial Received Date:	20211019 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101374457(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211014 CCYYMMDD	20211014 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101374457

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_04285882 CA2021AMR102648 CA-PFIZER INC-202101374457

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			52 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04790127 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Injection related reaction

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)

MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Injection related reaction	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Asthma
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
		615 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INJECTION RELATED REACTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Injection related reaction		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Injection related reaction		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a non-interventional study report from a contactable other health professional. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report is No E2B_04285882. (Linked Regulatory No E2B_04022832). This information was initially reported to Health Canada on 14Jun2021 from an unknown Market Authorization Holder AER# CA2021AMR102648.

A 52-year-old male subject received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 prophylaxis; mepolizumab (manufacturer unknown), subcutaneous from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 100 mg for asthma. The subject's medical history and concomitant medications were not reported. The subject experienced injection related reaction on an unspecified date. Seriousness Criteria included death and other medically important conditions. The action taken in response to the event for mepolizumab was unknown. The subject died on an unspecified date. It was not reported if an autopsy was performed. Outcome of event was fatal.

The reporter's assessment of the causal relationship of the event with the suspect products was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on known drug safety profile, there is reasonable possibility of causal association between the event injection site reaction and BNT162B2.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Injection related reaction	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
	Other studies

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04791195 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211020 CCYYMMDD
	HC Initial Received Date:	20211020 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-350499(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211012 CCYYMMDD	20211012 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2021-350499

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
irms QMODERNAP	CA-irms-MDCA21-03355 CA-MODERNATX, INC.-MOD-2021-350499

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			17 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04791195 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

ATIA - 19(1)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMM		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04791195 (0)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FOUND DEAD IN THE BEDROOM

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a non-health professional and describes the occurrence of DEATH (Found dead in the bedroom) in a 17-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.

No Medical History information was reported.

In [redacted] 2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 2021 The cause of death was not reported. It is unknown if an autopsy was performed.

No relevant concomitant medications were reported.
Treatment information was unknown.

Patient was found dead in the bedroom, few days after 2nd dose of Moderna vaccine.

Company comment: This case involves a 17-year-old male subject with unknown medical history who experienced the serious unlisted adverse event of death a few das after receiving his second dose of mRNA-1273. The patient was found dead in his bedroom. No further information is currently available on the reason of his death or events that may have resulted in death. The reporter declined further information on his name or address.

The benefit-risk relationship of mRNA-1273 is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case involves a 17-year-old male subject with unknown medical history who experienced the serious unlisted adverse event of death a few das after receiving his second dose of mRNA-1273. The patient was found dead in his bedroom. No further information is currently available on the reason of his death or events that may have resulted in death. The reporter declined further information on his name or address.

The benefit-risk relationship of mRNA-1273 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04791429 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211020 CCYYMMDD
	HC Initial Received Date:	20211020 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-350527(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211012 CCYYMMDD	20211012 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2021-350527

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2021-350527

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			27 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Drug abuser NOS
26.0	Drug addiction

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug abuse	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug abuse	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DRUG OVERDOSE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug abuse		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug abuse		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death) and DRUG ABUSE (Drug overdose) in a 27-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.

The patient's past medical history included Depression.

On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (Death) (seriousness criteria death and medically significant) and DRUG ABUSE (Drug overdose) (seriousness criterion medically significant). The patient died on an unknown date. The reported cause of death was drug overdose and Drug addiction. It is unknown if an autopsy was performed. At the time of death, DRUG ABUSE (Drug overdose) outcome was unknown.

The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.

Concomitant medication was not reported.
Treatment information was not reported.

Company Comment:
The case concerns a 27-year-old-male patient with previous relevant medical history of drug abuse and depression, who experienced the unexpected events of drug abuse and died. The events occurred on unknown days after the vaccination with of Spikevax. patient's medical history of drug abuse and depression remains as confounders. The benefit-risk relationship of Spikevax is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The case concerns a 27-year-old-male patient with previous relevant medical history of drug abuse and depression, who experienced the unexpected events of drug abuse and died. The events occurred on unknown days after the vaccination with of Spikevax. patient's medical history of drug abuse and depression remains as confounders. The benefit-risk relationship of Spikevax is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Depression	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug abuser NOS	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug addiction	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04804161 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211022 CCYYMMDD	
	HC Initial Received Date: 20211022 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101392651(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211018 CCYYMMDD	20211018 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101392651

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101392651

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Collapse of lung
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung disorder NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung disorder NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

KNOWS "FULLY VAAXED" PERSONS THAT HAVE DIED / ONE OF THEM WAS A PRETTY GOOD FRIEND THAT HE KNEW FOR YEARS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THEY PUT HIM ON A VENT AND BLEW UP HIS LUNGS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lung disorder NOS		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Lung disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a non-contactable consumer or other non-healthcare professional via the Medical Information Team. A male patient of an unspecified age received the second dose of BNT162B2 (COMIRNATY) via unspecified route of administration on unspecified date (batch/lot number was not reported) as DOSE 2, SINGLE and the first dose of BNT162B2 (COMIRNATY) via unspecified route of administration on unspecified date (batch/lot number was not reported) as DOSE 1, SINGLE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The consumer noted that he knows "fully vaaxed" persons that have died. He stated nobody he knows of has died from COVID. He stated, "I don't know, makes a guy wonder." One of them was a pretty good friend that he knew for years. The patient was double vaaxed, went to PRIVACY and didn't come back. They put him on a vent and blew up his lungs. "They should have given him a real drug like Ivermectin." The patient died on an unspecified date. It was unknown at the time of this report if an autopsy was performed.

No follow-up attempts are possible; information about the batch/numbers cannot be obtained. No further information is expected.
Comirnaty approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Collapse of lung	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04841533 (3)	Page#1
Canada Vigilance Adverse Reaction Report	**HC Latest Received Date:**	20211227 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101468129(4)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20211027 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211214 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-202101468129

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-202101468129

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04883003, (2) E2B_04883007, (2) E2B_04883006, (2) E2B_04883003, (2) E2B_04883007, (2) E2B_04883006, (2) E2B_04883003, (2) E2B_04883006, (2) E2B_04883007, (2) E2B_04869916, (2) E2B_04842245, (2) E2B_04841653, (2) E2B_04877665, (2) E2B_04869942, (2) E2B_04877680, (2) E2B_04877644, (2) E2B_04877639, (2) E2B_04877647, (2) E2B_04877584, (2) E2B_04877679, (2) E2B_04877620, (2) E2B_04677486, (2) E2B_04707931, (2) E2B_04703895, (2) E2B_04704132, (2) E2B_04707963, (2) E2B_04707954, (2) E2B_04883006, (2) E2B_04883007, (2) E2B_04883003

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

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Canada Vigilance AER#:	E2B_04841533 (3)	Page#2

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNKNOWN CAUSE OF DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer. This consumer reported similar events for four family members. This is the first of 4 reports. A patient of unspecified age and gender received BNT162b2 (COMIRNATY; Lot Number: UNKNOWN), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. Ongoing medical history included congestive heart failure from an unknown date. The patient's concomitant medications were not reported. On an unknown date, the reporter stated that the patient had congestive heart failure and died from the vaccine. The cause of death was not provided. It was not reported if an autopsy was performed.

The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Amendment: This follow-up report is being submitted to amend previously reported information: to amend validity.

Amendment: This follow-up report is being submitted to allow appropriate reporting to health authorities.

Follow-up (14Dec2021): This follow-up is being submitted to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congestive heart failure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

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Relevant medical history/ Concurrent conditions text (B.1.7.2)	

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04841653 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211229 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101468128(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211027 CCYYMMDD	20211227 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2) CA-PFIZER INC-202101468128

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101468128

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04841533

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			19 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAD THREE BLOOD CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team.

A 19-year-old consumer (patient) of unknown gender regarding PFIZER-BIONTECH COVID-19 VACCINE .A 19-years-old patient of an unspecified gender received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced died on an unspecified date , had three blood clots on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Outcome of blood clots was unknown.

The lot number for [BNT162], was not provided and will be requested during follow up

Follow-up (27Dec2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

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Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04841653 (1)	Page#5

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04842245 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211217 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101468126(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211027 CCYYMMDD	20211213 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101468126

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101468126

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04841533

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04842245 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 12 Hours	**Last period (B.4.k.13.2)** 12 Hours	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DROPPED DEAD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
12 Hours	12 Hours	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team. The reporter is patient's cousin.

A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose number unknown, single for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced dropped dead (death) (death) on an unspecified date. Patient dropped dead 12 hours after receiving the vaccine. Patient died on an unspecified date. It was unknown if an autopsy was performed.

The lot number for the vaccine, bnt162b2, was not provided and will be requested during follow up.

Follow-up (13Dec2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04842245 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Health Canada / Santé Canada

ATIA - 19(1)

Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Tunney's Pasture AL: 1908C
Ottawa, ON K1A 0K9
Tel (toll-free): 1-866-234-2345
Fax (toll-free): 1-866-678-6789
HC.Canada.Vigilance.SC@canada.ca

[redacted]

August 9, 2021

Re: Adverse Reaction Number 952325

Dear [redacted]

Thank you for your calls to the Canada Vigilance Program (CVP) on May 28, July 6 and August 4, 2021, regarding Zofran. We would like to express our deepest sympathy to you and your family for your loss and understand that this must be a difficult situation for you. We appreciate the time you took to call in about this tragic event and we apologize for the delay in our response but hope the information we provide will be helpful.

The information that you included in your call has been recorded in the Canada Vigilance Program database. The report has been assigned the Adverse Reaction Number 952325. Please reference the respective report number should you wish to report additional information on this event. Please note that Health Canada will contact you about your report only if additional information is required for its surveillance activities.

The CVP is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions (ARs) to health products submitted by health professionals and consumers, who report voluntarily, and by manufacturers, distributors and hospitals, who are required to submit reports under the *Food and Drugs Act*. Consequently, we cannot provide you any legal advice but recommend you maintain all relevant documentation if you decide to pursue legal action.

The information from side effect reports as well as information from other sources of data is used to determine whether the benefits of a given health product continue to outweigh its risks and to take appropriate action to minimize any new risks. Such actions may include the update of the label of a health product in its authorized Canadian monograph, risk communication(s) to inform Canadians about possible new side effects and/or a recall of the product.

For consumer information on health products for sale in Canada, you may wish to consult the Drug Product Database. This site allows you to search the database and read the product monographs, which provide information including contraindications, warnings and precautions as well as adverse reactions associated with a particular product. As requested, the 4 product monographs Zofran, midazolam, morphine and lorazepam monographs have been attached as individual PDF files to this email.

Health Canada also has the Canada Vigilance Adverse Reaction Online Database, which is a subset of the database available from the adverse reaction database at Health Canada, and is updated monthly. The time period of the data presented remains 3 months behind, in order to account for data entry and quality control activities. You can use the Canada Vigilance Online Database to obtain information on Canadian AR reports that have been received for marketed health products, like Zofran.

For your concerns on the care your mother received at the hospital, you mentioned you were already in contact with the College of Physicians and Surgeons of Ontario. Any concerns related to the ethics of health care professionals, including unethical payoffs and any tools being used in hospitals for patient care must be reported to the profession's respective provincial colleges as the "practice of medicine" is provincially regulated. If needed, please see the contact information for the College of Physicians and Surgeons of Ontario below.

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College of Physicians and Surgeons of Ontario
80 College Street
Toronto, Ontario M5G 2E2
Toll Free: 1-800-268-7096 Ext. 603
Email: feedback@cpso.on.ca

For your questions regarding the COVID-19 vaccination campaign, it has been redirected to the Public Health Agency of Canada (PHAC). You may follow-up with them directly via their email phac.vrtfcorrespondencegtpv.aspc@canada.ca. For the latest information on COVID-19, as well as vaccines and safety, you may visit the Government of Canada's COVID-19 webpage.

If you would like to be kept informed of Health Canada's advisories, recalls and other communication on health products, you may subscribe to MedEffect.

Once again, we would like to extend our sincere condolences, and wish you the best.

Canada Vigilance Program
Marketed Health Products Directorate
Health Canada

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ATIA - 19(1)

From: Leung, Jessica (HC/SC)
Sent: 2021-06-01 1:54 PM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Cc: Canada Vigilance (HC/SC); Seguin, Michelle (HC/SC)
Subject: RE: PUB-001221 Voicemail escalation

Categories: COVID

Hi EFAX,

As a follow-up, I spoke with the [redacted] consumer and just took down her mother's death report to the Pfizer vaccine & subsequent Zofran use. It's related to this case and the Online Submission Confirmation Number is **20210601135303_93155**.

Just for awareness, the patient also had further follow-up questions which I was unable to answer so if you could provide me with the **AER #** to ensure whomever is assigned to this case gets the whole picture. This also involves questions about the COVID-19 vaccination so I'm cc'ing Michelle Seguin as well.

Regards,
Jessica

From: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Sent: 2021-06-01 1:41 PM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC) <hc.hpfb.mhpseib.efax-biiepsc.dgpsa.sc@canada.ca>
Cc: Leung, Jessica (HC/SC) <jessica.leung@canada.ca>
Subject: FW: PUB-001221 Voicemail escalation

Hello EFAX,
Please see AR report below for DE
Once DE, could you please provide the AER number to Jessica (cc here)
Thank you ☺
Lynda

From: Litowitz, Paul (HC/SC) <paul.litowitz@canada.ca>
Sent: 2021-05-31 4:32 PM
To: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Cc: Leung, Jessica (HC/SC) <jessica.leung@canada.ca>
Subject: RE: Voicemail escalation

Yes please, most likely to Jessica. Thanks!

From: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Sent: 2021-05-31 11:57 AM
To: Litowitz, Paul (HC/SC) <paul.litowitz@canada.ca>
Cc: Leung, Jessica (HC/SC) <jessica.leung@canada.ca>
Subject: RE: Voicemail escalation

Good morning Paul,

ATIA - 19(1)

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Should I assigned this is PUB correspondence? Please let me know.

Thanks,

Shun

From: Litowitz, Paul (HC/SC) <paul.litowitz@canada.ca>
Sent: 2021-05-31 11:52 AM
To: Stienburg, Lynn (HC/SC) <lynn.stienburg@canada.ca>; Aubertin, Nancy (HC/SC) <nancy.aubertin@canada.ca>
Cc: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>; Leung, Jessica (HC/SC) <jessica.leung@canada.ca>
Subject: RE: Voicemail escalation

Hi Nancy,
Area code [redacted] is part of the [redacted] region's territory in PROS. Would it be possible to update CRMU's records accordingly?
Paul

From: Stienburg, Lynn (HC/SC) <lynn.stienburg@canada.ca>
Sent: 2021-05-31 11:37 AM
To: Litowitz, Paul (HC/SC) <paul.litowitz@canada.ca>
Cc: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Subject: RE: Voicemail escalation

[redacted] responsibility for this area code was largely put in place a number of years ago for distribution of reports for processing. Limited calls come in from this area code. I have no working knowledge related to delivery of services, health system contacts, provincial roles and the delivery of healthcare In the province of [redacted]

For consideration moving forward as to whether area code [redacted] should continue to be supported by Atlantic?
Thank you,
- Lynn

From: Stienburg, Lynn (HC/SC)
Sent: 2021-05-31 12:27 PM
To: Litowitz, Paul (HC/SC) <paul.litowitz@canada.ca>
Cc: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Subject: RE: Voicemail escalation

Hi Paul and Myriam,
I would appreciate your direction in this case. Who would respond to the caller as they are discussing lawsuits? I am not familiar with the healthcare system in [redacted]
Thank you,
- Lynn

From: Dionne, Alexandre (HC/SC) <alexandre.dionne@canada.ca>
Sent: 2021-05-31 11:52 AM
To: Stienburg, Lynn (HC/SC) <lynn.stienburg@canada.ca>
Cc: Litowitz, Paul (HC/SC) <paul.litowitz@canada.ca>
Subject: Voicemail escalation

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ATIA - 19(1)

Hello,

We received a call over the weekend from a woman who was calling to report that her mother had passed away following an AR to the medication Zofran, which was administered while she was in the hospital last week. She was also questioning why this drug was administered to her mother in the first place and why it's approved by Health Canada, citing information she found online concerning multiple lawsuits in the US, and considering recourses.

As I do not have much experience yet and this call has potential medical/legal ramifications, I felt more comfortable escalating this case.

Caller:
[redacted]on behalf of her deceased mother.
[redacted]

Thank you !

Alexandre Dionne

Support Officer/ Agent de soutien
MHPSEIB / BIIEPSC
Marketed Health Products Directorate (MHPD) / Direction des produits de santé commercialisés (DPSC)
Health Canada / Santé Canada
alexandre.dionne@canada.ca

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"Safety Report ID: CA-DHPR-20220204163929_129195

Type of Report: Follow-up

HC Ref. No [redacted]

Reporter File No.:

Transmission Date: 20220204

First Name: [redacted]

Last Name [redacted]

Telephone: [redacted]

Ext.:

Address:

City: [redacted]

Province/Territory: [redacted]

Postal Code:

Email address [redacted]

Organization:

Reporter Type: Other health professional

Patient ID: [redacted]

Age: 71 Year(s)

Sex: Female

Height:

Weight:

Med History: Multiple CT scans with contrast agents leading up to the hospitalization, diabetes, congestive heart failure

Allergies:

Serious Death: Yes

Date of Death:

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Serious Life-Threatening:

Serious Disability:

Serious Hospitalization:

Serious Congenital Anomaly:

Serious Other:

Serious Other Explain:

Reaction 1

Outcome: Died

Reaction Start Date: 2021[redacted]

Reaction End Date:

Reaction Description: The reporter still strongly feels that the original reason her mother was in the hospital in the first place was with a headache, vomiting, diarrhea, upper left quadrant pain which could have been related to her first Pfizer shot. The patient's daughter also wanted to add that she just received her mother's autopsy results, which confirms she had fatal levels of morphine (134 when max is 120, with a margin of error of +/- 14) but they did not test for Zofran levels. She had some cysts on her kidney and ultimately passed away from an ischemic stroke. The patient is skeptical a proper full autopsy was done on her mother's body. Upon reviewing the hospital's EMAR system records, where [redacted] decided that after she had a stroke, she would be undergoing a palliative regimen without the reporter's consent. The physician, Dr[redacted] initiated a DNR protocol while the patient was still undergoing post-stroke treatment. They tested the patient for COVID-19 while she was in the hospital and she was negative as well. She would like me to emphasize that she has major concerns that the funding for medication is being highly biased towards pushing COVID-19 related treatments into Canadians due to profit for big pharma (e.g. become long term patients for big pharmaceutical companies). Funding partnerships like these are violations against human rights. Verbal report taken by[redacted] on Feb 4, 2022.

Suspect Product 1

DIN #/NPN #: Zofran

Product Name:

Strength:

Strength other:

Dosage form:

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Manufacturer:

Lot #:

Expiry date:

Product start date:

Product end date:

Dose:

Frequency:

Route of administration:

Route of administration - Other:

Indication:

Reported to Mfr:

Date reported to Mfr:

Mfr Reference number:

Drug action taken:

Dechallenge:

Rechallenge:

Suspect Product 2

DIN #/NPN #: 02509210

Product Name: PFIZER-BIONTECH COVID-19 VACCINE

Strength:

Strength other:

Dosage form:

Manufacturer:

Lot #:

Expiry date:

Product start date:

Product end date:

Dose:

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Frequency:

Route of administration:

Route of administration - Other:

Indication:

Reported to Mfr:

Date reported to Mfr:

Mfr Reference number:

Drug action taken:

Dechallenge:

Rechallenge:

Concomitants: First dose of Pfizer vaccine. Also given morphine and midazolam while patient was in the hospital for treatment. She has already started a [redacted] investigation, file number 1117323.

Test/Lab results narrative:"

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Canada Vigilance AER#:	E2B_04843733 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211103 CCYYMMDD	
	HC Initial Received Date: 20211103 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-363285(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20211025 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211025 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2021-363285

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-MODERNATX, INC.-MOD-2021-363285

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_04561608

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 29 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyslexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyslexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Interchange of vaccine products	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Not applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Interchange of vaccine products	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Mental disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Mental disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retardation mental	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retardation mental	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Retinal detachment	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal detachment	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal tear	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal tear	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal thinning	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal thinning	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
		2021[redacted] CCYYMMDD	
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETINAL TEAR

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Retinal tear		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Retinal tear		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETINAL DETACHMENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Retinal detachment		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Retinal detachment		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ALL DSM 5

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Mental disorder		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Mental disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSLEXIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dyslexia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyslexia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cancer		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Neoplasm malignant		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETINAL THINNING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Retinal thinning
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Retinal degeneration

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETARDATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Retardation mental
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Intellectual disability

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERCHANGE OF VACCINE PRODUCTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Interchange of vaccine products
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Interchange of vaccine products

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
1 Days		Unknown

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Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Heart attack), RETINAL TEAR (Retinal tear), RETINAL DETACHMENT (Retinal detachment), MENTAL DISORDER (All DSM 5), DYSLEXIA (Dyslexia), NEOPLASM MALIGNANT (Cancer), RETINAL DEGENERATION (Retinal thinning), INTELLECTUAL DISABILITY (Retardation) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.

Co-suspect product included non-company product BNT162B2 for COVID-19 immunisation.

The patient's past medical history included Meningococcal meningitis (Hospitalisation prolonged:Yes, No treatment received) in May 2018, Mental disorder NOS and Electroconvulsive therapy (Hospitalised for 4 days and hospitalization prolonged, Treatment received :unknown) on [redacted]-2021.

On [redacted]2021, the patient received second dose of BNT162B2 (unknown route) 1 dosage form.
On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On [redacted]2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant). On an unknown date, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criteria death, hospitalization and medically significant), RETINAL TEAR (Retinal tear) (seriousness criterion medically significant), RETINAL DETACHMENT (Retinal detachment) (seriousness criterion medically significant), MENTAL DISORDER (All DSM 5) (seriousness criterion medically significant), DYSLEXIA (Dyslexia) (seriousness criterion medically significant), NEOPLASM MALIGNANT (Cancer) (seriousness criterion medically significant), RETINAL DEGENERATION (Retinal thinning) (seriousness criterion medically significant) and INTELLECTUAL DISABILITY (Retardation) (seriousness criterion medically significant). The patient died on [redacted]2021. The reported cause of death was Heart attack. It is unknown if an autopsy was performed. At the time of death, RETINAL TEAR (Retinal tear), RETINAL DETACHMENT (Retinal detachment), MENTAL DISORDER (All DSM 5), DYSLEXIA (Dyslexia), NEOPLASM MALIGNANT (Cancer), RETINAL DEGENERATION (Retinal thinning), INTELLECTUAL DISABILITY (Retardation) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. Not Provided

No relevant concomitant and treatment medications were reported.

Company comment
This is a case of Interchange of vaccine products for this 29-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Myocardial infarction with a fatal outcome, Retinal tear, Retinal detachment, Mental disorder, Dyslexia, Neoplasm malignant, Retinal degeneration, and Intellectual disability. The events occurred on an unknown day after receiving the most recent COVID vaccine BNT162B2 (Pfizer vaccine) with date of administration [redacted] 2021. However, mRNA-1273 was also administered prior to the patient receiving the BNT162B2 for COVID-19 immunization. (Date of administration of Moderna product is in question per source document). The benefit-risk relationship of mRNA-1273 is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This is a case of Interchange of vaccine products for this 29-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Myocardial infarction with a fatal outcome, Retinal tear, Retinal detachment, Mental disorder, Dyslexia, Neoplasm malignant, Retinal degeneration, and Intellectual disability. The events occurred on an unknown day after receiving the most recent COVID vaccine BNT162B2 (Pfizer vaccine) with date of administration [redacted] 2021. However, mRNA-1273 was also administered prior to the patient receiving the BNT162B2 for COVID-19 immunization. (Date of administration of Moderna product is in question per source document). The benefit-risk relationship of mRNA-1273 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Electroconvulsive therapy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
202[redacted] CCYYMMDD	Unknown	

Comments (B.1.7.1g)

Hospitalised for 4 days and hospitalization prolonged, Treatment received :unknown

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Meningococcal meningitis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
201805 CCYYMM	Unknown	
Comments (B.1.7.1g)		
Hospitalisation prolonged:Yes, No treatment received		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Mental disorder NOS	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date (B.1.8e)**
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date (B.1.10.8e)**
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04847583 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211222 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101495439(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211019 CCYYMMDD	20211220 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101495439

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101495439

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04852939, (2) E2B_04852939, (2) E2B_04852939

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04847583 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

I HAVE A FRIEND WHO HAS LOST 2 LOVED ONES FROM YOUR VACCINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team.

A patient of unspecified age and gender received BNT162B2 (COMIRNATY, solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose number unknown, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter stated that the reporter has a friend who has lost 2 loved ones from the vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed.

The lot number for BNT162b2 was not provided and will be requested during follow up.

Follow-up (20Dec2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04852939 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211222 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101505893(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20211019 CCYYMMDD	20211220 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101505893

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101505893

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04847583, (2) E2B_04847583, (2) E2B_04847583

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04852939 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

I HAVE A FRIEND WHO HAS LOST 2 LOVED ONES FROM YOUR VACCINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team.

A patient of unspecified age or gender received BNT162B2 (COMIRNATY, solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose number unknown, single for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported, "I have a friend who has lost 2 loved ones from your vaccine". The patient died on an unspecified date. It was not reported if an autopsy was performed.

The lot number for BNT162B2, was not provided and will be requested during follow up.

Follow-up (20Dec2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04883003 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211229 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101565276(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211027 CCYYMMDD	20211227 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101565276

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101565276

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04841533, (2) E2B_04841533, (2) E2B_04841533, (2) E2B_04841533

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04883003 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNKNOWN CAUSE OF DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer. This consumer reported similar events for four family members. This is the fourth of 4 reports. A patient of unspecified age and gender received BNT162b2 (COMIRNATY; Lot Number: UNKNOWN), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. Ongoing medical history included congestive heart failure from an unknown date. The patient's concomitant medications were not reported. On an unknown date, the reporter stated that the patient had congestive heart failure and died from the vaccine. The cause of death was not provided. It was unknown if an autopsy was performed.

Follow-up (27Dec2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congestive heart failure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04883003 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04883006 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211228 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101565222(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20211027 CCYYMMDD	20211223 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101565222

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101565222

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04841533, (2) E2B_04841533, (2) E2B_04841533, (2) E2B_04841533

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04883006 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNKNOWN CAUSE OF DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team.

A patient of unspecified age and gender received BNT162b2 (COMIRNATY; Lot Number: UNKNOWN), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. Ongoing medical history included congestive heart failure from an unknown date. The patient's concomitant medications were not reported. On an unknown date, the reporter stated that the patient had congestive heart failure and died from the vaccine. The cause of death was not provided. It was not reported if an autopsy was performed.

The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Follow-up (23Dec2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congestive heart failure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04883006 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04883007 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211228 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101565275(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211027 CCYYMMDD	20211223 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101565275

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101565275

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04841533, (2) E2B_04841533, (2) E2B_04841533, (2) E2B_04841533

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04883007 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNKNOWN CAUSE OF DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team.

A patient of unspecified age and gender received BNT162b2 (COMIRNATY; Lot Number: UNKNOWN), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. Ongoing medical history included congestive heart failure from an unknown date. The patient's concomitant medications were not reported. On an unknown date, the reporter stated that the patient had congestive heart failure and died from the vaccine. The cause of death was not provided. It was not reported if an autopsy was performed.

The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Follow-up (23Dec2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congestive heart failure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)		
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04886899 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220202 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101556198(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20211109 CCYYMMDD	20220125 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101556198

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101556198

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			51 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

ATIA - 19(1)

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Canada Vigilance AER#:	E2B_04886899 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04886899 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE DROPPED DEAD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable Nurse. A 51 year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as DOSE NUMBER UNKNOWN, SINGLE for COVID-19 immunisation. He died in [redacted] 2021 and he was vaccinated. He was out doing some exercises and he dropped dead. It was unknown if autopsy done. Outcome of the event was fatal.

Follow-up (25Jan2022): This follow-up is being submitted to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The information currently provided is too limited to make a meaningful medical assessment. However, per company causality assessment guidance, the event of death with unknown cause is assessed as related until the cause of death is clarified.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04886899 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04886909 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211112 CCYYMMDD	
	HC Initial Received Date: 20211112 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101555942(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20211109 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211109 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-202101555942

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-202101555942

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 56 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04886909 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 3 Days	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY FROM A HEART ATTACK 3 DAYS AFTER HIS 1ST DOSE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heart attack

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Myocardial infarction

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
3 Days		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (patient's friend). A 56-year-old male patient received the first dose of bnt162b2 (COMIRNATY) via an unspecified route of administration on an unspecified date (Lot number was not reported) as DOSE 1, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced passed away from a heart attack 3 days after his 1st dose on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible. No further information expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04896059 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211116 CCYYMMDD
	HC Initial Received Date:	20211116 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-378352(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211108 CCYYMMDD	20211108 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2021-378352

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2021-378352

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04896059 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FRIEND DIED AFTER RECEIVING THE MODERNA VACCINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by an other health care professional and describes the occurrence of DEATH (Friend died after receiving the Moderna vaccine) in a patient of an unknown age and gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.

No relevant concomitant medication information provided.

No relevant treatment medication information provided.

Company Comment - This case concerns a patient of an unknown age and gender with no relevant medical history, who experienced the unexpected event of Death. The event occurred 22 days after receiving an unknown dose number of mRNA-1273 Vaccine with a fatal outcome. The rechallenge was unknown since only information about an unknown dose number was disclosed. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case concerns a patient of an unknown age and gender with no relevant medical history, who experienced the unexpected event of Death. The event occurred 22 days after receiving an unknown dose number of mRNA-1273 Vaccine with a fatal outcome. The rechallenge was unknown since only information about an unknown dose number was disclosed. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04922770 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211201 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101618162(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20211117 CCYYMMDD	20211125 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101618162

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101618162

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			36 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Chemical exposure
26.0	Hemoptysis
26.0	Poor quality vaccine administered
26.0	Product contamination chemical
26.0	Product contamination microbial

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Chemical exposure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chemical exposure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Melena	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Melena	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Poor quality vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Poor quality vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Product contamination chemical	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Product contamination chemical	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Product contamination microbial	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Product contamination microbial	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THERE WAS PARASITE AND OXIDE FOUND WHICH IS IN YOUR VACCINE.

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Product contamination microbial
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Product contamination microbial

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THERE WAS PARASITE AND OXIDE FOUND WHICH IS IN YOUR VACCINE.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Product contamination chemical
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Product contamination chemical

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THERE WAS PARASITE AND OXIDE FOUND WHICH IS IN YOUR VACCINE.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chemical exposure
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Exposure to toxic agent

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THERE WAS PARASITE AND OXIDE FOUND WHICH IS IN YOUR VACCINE.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Poor quality vaccine administered
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Poor quality product administered

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED IN A POOL OF BLACK BLOOD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Melena
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Melaena

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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2 Weeks	2 Weeks	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer. A 36-year-old female patient received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient died in a pool of black blood on an unspecified date. The reporter stated that there was parasite and oxide found which was in the vaccine. The patient underwent lab tests and procedures which included: there was oxide in the vaccine, parasitic test: there was parasite in the vaccine. The outcome of event was fatal. It was unknown if autopsy was done to patient.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Amendment: This follow up report is being submitted to amend previously reported information: updated the event "died in a pool of black blood" coding from "hemoptysis" to "melena".

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Investigation NOS	There was oxide	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Parasitic test	There was parasite	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chemical exposure	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Poor quality vaccine administered	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemoptysis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Product contamination microbial	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	Episode name (B.1.7.1a.2) Product contamination chemical	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04922770 (1)	Page#7

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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ATIA - 19(1)
HC-SC REC'D 15-JN-2021

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A.1 - Type of report* [see Options]	Initial
A.2 - Health Canada (HC) Reference No. (for follow-up reports only) [18AN]	
A.3 - Organization File No. [100AN]	[redacted]
A.4 - Date report submitted [YYYY-MM-DD]	2021-06-15
A.5 - Documentation date* [YYYY-MM-DD]	[redacted]2021
A.6a - Organization contact first name* [35AN]	
A.6b -Last name* [35AN]	[redacted]
A.7.a - Phone no.* [14N]	
A.7.a- ext. [5N]	
A.7.b - Email [100AN]	[redacted]
A.7.c - Fax [14N]	
A.8 - Organization name* [120AN]	[redacted]
A.9- Source of report (profession) [see Options]	
A.10 - Heath Canada institutional ID (If ID provided, no need to provide address) [9AN]	[redacted]
A.11 - Address [100AN]	
A.12 - City [40AN]	[redacted]
A.13 - Province/Territory [see Options]	

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A.14 - Postal code [6AN]	
A.15.a - Reason for seriousness: Death* [see Options]	Life-threatening
A.15.a - Date of death* [YYYY-MM-DD]	
A.15.b - Reason for seriousness: Life-threatening* [see Options]	
A.15.c - Reason for seriousness: Disability* [see Options]	
A.15.d - Reason for seriousness: Congenital malformation* [see Options]	
A.15.e - Reason for seriousness: Caused/prolonged in-patient hospitalization* [see Options]	
A.15.f - Reason for seriousness: Required medical intervention to avoid any of (a) to (e)* [see Options]	
B.1 - Patient ID (e.g. initials, record no.) [10AN]	
B.2 - Sex [see Options]**	Male
B.3.a - Age [5N]**	
B.3.b - Age unit [see Options]**	76 years
B.4. Height (cm) [3N]	
B.5. Weight (kg) [6N]	
B.6 - Known medical conditions and relevant lifestyle	

ATIA - 19(1)

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factors* [1500AN]	
B.7 - Known allergies* [500AN]	
C.1 - Did the patient recover?* [see Options]	Not recovered
C.2 - Reaction start date* [YYYY-MM-DD]	[redacted]2021
C.3 - Reaction end date* [YYYY-MM-DD]	[redacted]2021
C.4 - Description of the serious adverse drug reaction(s) [200N]**	1 week post Pfizer covid vaccination as an outpatient presented to Emerg with Left side deficits, aphasic found to have basilar artery CVA admitted to ICU. Unsure if CVA is related to Vaccine as patient had other risk factors or may be spontaneous in origin.
D.1 - Drug identification number (DIN)* [35AN]	
D.2 - Identifying code for urgent public health need drugs (if applicable) [35AN]**	
D.3 - Brand name (per product label) [70AN]**	pfizer COVID 19 Vaccine
D.4 - Common/proper name (active ingredient) [70AN]	
D.5 - Strength [8N]	
D.5 - Strength unit [see Options]	
D.5 - Other strength unit [50AN]	
D.6 - Dose [8N]	
D.6 - Dose unit [see Options]	<N/S>

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D.6 - Other dose unit [50AN]	
D7 - Frequency [100AN]	<N/S>
D.8 - Dosage form [50AN]	
D.9 - Route of administration [see Options]	<N/S>
D.9 - Other route of administration [100AN]	
D.10 - Product start date* [YYYY-MM-DD]	
D.11 - Product end date* [YYYY-MM-DD]	
D.12 - Indication [250AN]	CoVID PRevention
D.13 - Lot no. [35AN]	
D.14 - Expiry date [YYYY-MM-DD]	
D.15.a - Manufacturer name* [70AN]	
D.15.b - Did you also report to the manufacturer? [see Options]	
D.15.c - Date reported [YYYY-MM-DD]	
D.15.d - Reference no. (if known) [30AN]	
D.16 - What action was t aken? [see Options]	Not Applicable
D.17 - Did the reaction stop if dose was reduced or removed? [see Options]	Not Applicable
D.18 - Did the reaction return with reintroduction of	Not Applicable

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the product? [see Options]	
E - Known therapeutic products taken or used at the same time the reaction occurred* [2000AN]	
F.1 - Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to assessment of the serious adverse drug reaction(s). [18000AN]	
F.2 - "Mandatory" or "Voluntary" report	Mandatory

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: [redacted]
Sent: 2021-06-17 1:12 PM
To: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC); Seguin, Michelle (HC/SC)
Subject: RE: [EXTERNAL] Health Canada Follow-Up Request (PFIZER COVID-19 VACCINE)

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Michelle, Red Category

Good Afternoon,

Here is the information you requested on this patient.

- As the patient did not receive the Pfizer vaccine at our facility, I am unable to answer if it was his first or second dose
- It is documented the patient did not have any known past medical history "None known – son states he has not seen a doctor in years" and prior to admission was not on any regularly prescribed medications
- At time of adverse event, patient was COVID-negative
- It is undetermined if this adverse event is directly related to the patient's presenting diagnosis – stroke
    - It is documented the patient had the vaccine 1 week prior to presenting to hospital
    - The patient underwent
        - Bloodwork
        - Diagnostic imaging (CT, MRI)
        - EEG
        - ICU admission
        - Intubation
        - Thrombectomy – unsuccessful
    - The patient passed away [redacted]

Please let me know if you require any further information.

Thank you,

[redacted]

From: Seguin, Michelle (HC/SC) [mailto:michelle.seguin@canada.ca] **On Behalf Of** Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: Thursday, June 17, 2021 7:52 AM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: [EXTERNAL] Health Canada Follow-Up Request (PFIZER COVID-19 VACCINE)

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ATIA - 19(1)
EXTERNAL

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Re: Health Canada Follow-Up Clarification Request

Good afternoon [redacted]

We are contacting you today to confirm receipt of the adverse event following immunization (AEFI) report submitted to the Canada Vigilance Program on **June 15th, 2021** regarding suspect products: **PFIZER COVID-19 VACCINE**.

As the result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified the present individual case safety reports (ICSRs) where clarification is needed in order to complete the case evaluation.

Canada Vigilance Case Number	Clarification Requested
000954410 (Organization/Institutional File No. [redacted]	Would you kindly have any information of the following: ☒ Information about the COVID-19 immunization: Was this the patient's first or second dose of Pfizer vaccine and timing of first vaccine dose (as relevant). ☒ Clinical information regarding the patient's current medical history, including any potential cardiovascular risk factors (e.g., diabetes, smoking history, hypertension, hyper-cholesterol or hyperlipidemia and history of ischemic heart diseases), any history of blood clotting, and patient's concurrent medications. ☒ Patient's COVID-19 status at the time of the adverse event? ☒ Information about any presenting symptoms and any pre-hospital treatment(s) related to the adverse event, including the following information as available: i. all side effects experienced post vaccination including a description of the side effect(s), time to onset, course and outcome e.g. if had fatigue time to onset, duration, if resolved, etc. ii. Additional information regarding any pre-hospital symptoms of the presenting CVA including start date, course and any treatments the patient received prior to arrival at hospital, and timing of any medications taken in the 24 hours prior to the event (including reason for e.g. regular prescribed medication vs PRN (and indication, if relevant).

May you please kindly respond to both myself, Michelle Séguin: michelle.seguin@canada.ca in addition to the Canada Vigilance COVID-19 Vaccine generic account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca).

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Or, if you prefer, you may fax the requested information to the Canada Vigilance Program fax at 1-866-678-6789; please cite **case number 000954410.**

If you require further information within the scope of this request, please do not hesitate to contact me.

We thank you once again for your time.

Sincerely,

Michelle Séguin
The Canada Vigilance Program, Health Canada

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

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Canada Vigilance AER#:	E2B_04927481 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211123 CCYYMMDD
	HC Initial Received Date:	20211123 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101637375(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211112 CCYYMMDD	20211112 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101637375

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101637375

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) E2B_04927489, (2) E2B_04927499

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04927481 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heart attack
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Myocardial infarction

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a non-contactable consumer via medical information reporting same event under the same suspect product for three patients. This is one of three reports.

A male patient of an unspecified age received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced heart attack on an unspecified date. Reporter stated that she knew 2 younger males (exact ages unknown) who both died after heart attacks after receiving the Pfizer Covid-19 vaccine. Reporter also stated that she knew another male (exact age unknown) who also died from a heart attack after receiving the Pfizer Covid-19 vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Heart attack

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04927481 (0)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04927489 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211123 CCYYMMDD
	HC Initial Received Date:	20211123 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101637374(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211112 CCYYMMDD	20211112 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101637374

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101637374

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) E2B_04927481, (2) E2B_04927499

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04927489 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heart attack
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Myocardial infarction

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a non-contactable consumer via medical information reporting same event under the same suspect product for three patients. This is one of three reports.

A male patient of an unspecified age received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced heart attack on an unspecified date. Reporter stated that she knew 2 younger males (exact ages unknown) who both died after heart attacks after receiving the Pfizer Covid-19 vaccine. Reporter also stated that she knew another male (exact age unknown) who also died from a heart attack after receiving the Pfizer Covid-19 vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04927499 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211123 CCYYMMDD	
	HC Initial Received Date: 20211123 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101587574(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20211112 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211112 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-202101587574

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-202101587574

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04927489, (2) E2B_04927481

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04927499 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heart attack
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Myocardial infarction

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a non-contactable consumer via medical information reporting same event under the same suspect product for three patients. This is one of three reports.

A male patient of an unspecified age received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced heart attack on an unspecified date. Reporter stated that she knew 2 younger males (exact ages unknown) who both died after heart attacks after receiving the Pfizer Covid-19 vaccine. Reporter also stated that she knew another male (exact age unknown) who also died from a heart attack after receiving the Pfizer Covid-19 vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

ATIA - 19(1)

Canada Vigilance AER#:	E2B_04931677 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211124 CCYYMMDD	
	HC Initial Received Date: 20211124 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A825069()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211121 CCYYMMDD	20211121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	Company number (A.1.10.2) CA-AstraZeneca-2021A825069

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	E2B_04410794 [redacted] CA-AstraZeneca-2021A825069

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer. The report concerns a male patient (age not provided) of Unknown ethnic origin.

No medical history was reported. No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) 0.5 ml, via intramuscular route, on an unknown date. The patient died (MedDRA PT: Death) on an unspecified date.
Action taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable.

It was not known whether an autopsy was performed. The cause of death was death.

The event death was considered serious (death).

No lab data was available.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.CAUSE OF DEATH: DEATH
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case report concerns a patient with reported fatal outcome (PT: death) in association with AZD1222. Due to limited information regarding baseline characteristics of the subject before vaccination and further circumstances leading to the event, other relevant medical and family history of the patient, other concurrent diseases(cardiac disease, malignancy, kidney disease, liver disease) and concomitant medications, specific risk factors, autopsy details, etiological and complete diagnostic work-up(complete blood count, imaging study panel, cardiac markers, kidney function test, liver function tests), the evaluation did not find evidence to suggest a causal relationship between event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Canada Vigilance AER#:	E2B_04931677 (0)	

Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04933375 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220315 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-125883(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211119 CCYYMMDD	20220311 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2) CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-125883

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
HEALTHCANVIG HEALTHCANVIG 01001927719	CA-HEALTHCANVIG-E2B_04943036 CA-HEALTHCANVIG-E2B_04369581 CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-125883

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04369581

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - BRISTOL-MYERS SQUIBB

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		

Date of birth (B.1.2.1)	Age group (B.1.2.3)	Onset Age (B.1.2.2)
		102 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04933375 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ELIQUIS FILM COATED	
Active Substance names (B.4.k.2.2)		
apixaban		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2.5 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6)		
2.5 milligram, bid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Cerebrovascular accident prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	TOZINAMERAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
total		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
vial contains 6 doses of 0.3ml after dilution		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METOPROLOL	
Active Substance names (B.4.k.2.2)		
metoprolol		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
12.5 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6)		
12.5 milligram, bid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PERINDOPRIL	
Active Substance names (B.4.k.2.2)		
perindopril		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2 Milligram		
Dosage text (B.4.k.6)		
2 milligram		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN D3	
Active Substance names (B.4.k.2.2)		
vitamin d3		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02496992 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This case was initially received via Pfizer Inc (Reference number: 202101624815) on 19-Nov-2021. The most recent information was received on 11-Mar-2022 and was forwarded to BMS on 11-Mar-2022.
This spontaneous case was reported by a physician and describes the occurrence of DEATH in 102-year-old male patient who received apixaban (Eliquis) film-coated tablet for Cerebrovascular accident prophylaxis.

CO-SUSPECT PRODUCTS included tozinameran (Comirnaty) suspension for injection for COVID-19 immunisation.

On an unknown date, the patient started Eliquis (Oral), 2.5 milligram twice a day and Comirnaty (Intramuscular) total. DEATH occurred on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed.

For Eliquis(Oral), the reporter did not provide any causality assessments.
This case was received via Health Authority Canada (Reference number: CA-HEALTHCANVIG-E2B_04943036)
Most recent follow-up information received from the physician incorporated above includes: 11-Mar-2022. Reporter added, product attributes and narrative updated.

BMS Medical Evaluation Comment:
This patient who was on apixaban therapy along with tozinameran had died. Based on the limited information regarding the cause of death, autopsy report, it cannot be ascertained with reasonable possibility that apixaban contributed to the reported fatal event.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

BMS Medical Evaluation Comment:
This patient who was on apixaban therapy along with tozinameran had died. Based on the limited information regarding the cause of death, autopsy report, it cannot be ascertained with reasonable possibility that apixaban contributed to the reported fatal event.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04937087 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211230 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101189953(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210910 CCYYMMDD	20211221 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101189953

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101189953

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Neoplasm progression

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Feeling sick	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Feeling sick	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Neoplasm progression	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Neoplasm progression	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYING OF LUNG CANCER/DIED DAYS AFTER RECEIVING THE SHOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Neoplasm progression		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Neoplasm progression		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHE IMMEDIATELY FELL ILL/SICK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Feeling sick		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Malaise		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

The initial safety information received was reporting only non-serious adverse drug reactions. Upon receipt of follow-up information on 15Nov2021, this case now contains serious adverse reactions. Information processed together.

This is a spontaneous report from a contactable consumer (daughter-in-law) via medical information team. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on an unspecified date (Batch/Lot number was not reported) as dose 2, single for COVID-19 immunisation. Medical history included lung cancer: less than a week to live with lung cancer. Vaccination history included: Covid-19 vaccine (dose 1, MANUFACTURER UNKNOWN), for Covid-19 immunization.Concomitant medications were not reported. A doctor prescribed her mother-in-law (patient) who had less than a week to live with lung cancer the second dose and she immediately fell ill. Although the consumer knew the patient didn't die from the vaccine, she was unnecessarily sick for a vaccine that she really did not need. The doctor sent a nurse to the house with the vaccine, in hours she was sick, in a day and half she was unresponsive. The patient was dying of lung cancer and had days to live. The patient died days after receiving the shot, the consumer doesn't believe her death was because of the vaccine but didn't help either. The consumer doesn't think her mother-in-law should have had the shot in the first place since she was dying of cancer. The patient died of lung cancer on an unspecified date. It was unknown if an autopsy was performed. The outcome of "she immediately fell ill/sick" was unknown.

Follow-up (21Dec2021): This follow-up is being submitted to notify that the lot/batch number for (all) doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

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MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Lung cancer	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)
less than a week to live with lung cancer

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Neoplasm progression	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)
COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Canada Vigilance AER#:	E2B_04937087 (1)	Page#5

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04941652 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211221 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A832980()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20211124 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211217 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	Yes
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A832980

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** [redacted] CA-AstraZeneca-2021A832980

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)** 173 Centimeter	**Patient weight (B.1.3)** 81.6 Kilogram
Date of birth (B.1.2.1) 1954[redacted] CCYYMMDD	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 62 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Dizzy spells

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)
26.0	Dizzy spells

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 2		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Product used for unknown indication Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dizzy spells	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
INITIAL REPORTER		Yes
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dizzy spells	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
INITIAL REPORTER		Yes

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIZZY SPELLS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Dizzy spells
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Dizziness

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received by Canada from a consumer concerning a male patient of Caucasian ethnic origin of age 62 years, height 68 in, weight 180 lb.

No medical history was reported. No concomitant products were reported. Patient was healthy and hiked everyday.

The patient received Dose 1 of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for unknown indication, on an unknown date. The patient received Dose 2 of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for unknown indication, on an unknown date. On an unknown date, the patient experienced dizzy spells (preferred term: Dizziness). Dizzy spells started directly after 1st dose. Patient got tested after the dizzy spells began and found nothing.

It was not applicable if any action was taken with dose 1 and dose 2 of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. The patient died from the event on [redacted]2021.

An autopsy was performed. The cause of death was dizzy spells (confirmed at autopsy).

The event was considered serious due to seriousness criteria death and life threatening.

The reporter considered the following event(s) related to treatment with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)): dizzy spells. The reporter considered the following event(s) related to treatment with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)): dizzy spells.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

All required follow-up attempts have been completed to obtain the Lot / Batch number for COVID-19 VACCINE ASTRAZENECA, however the Lot / Batch number was not received.

Summary of follow-up information received by AstraZeneca/MedImmune on 17-DEC-2021 : Lot / Batch number follow-up attempts information was updated into the narrative.AUTOPSY DETERMINED CAUSE OF DEATH: DIZZY SPELLS

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Dizziness (reported as DIZZY SPELLS) is not listed in the company core data sheet of AZD1222. The cause of death was reported as dizzy spells. The patient's overweight could be considered a contributory risk factor for the event. Due to limited information on details of the event leading to death, the exact date of vaccination, patient's baseline health condition before the vaccination, relevant medical history, family history, concurrent diseases, concomitant medications, discussion on lifestyle and risk factors, etiologic and diagnostic workup (complete laboratory workup, imaging techniques), treatment details, the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Dizzy spells

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
Dr.	UNKNOWN	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
PRIVACY

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221215 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101654766(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211124 CCYYMMDD	20221213 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101654766

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_04459575 CA2021AMR157705 CA-PFIZER INC-202101654766

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			56 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Asthma
26.0	Product dose omission issue

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Asthma	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Interchange of vaccine products	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Product dose omission issue	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Asthma	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Interchange of vaccine products	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Product dose omission issue	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Asthma	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Interchange of vaccine products	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Product dose omission issue	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Asthma
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19 VACCINE/CHADOX

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Interchange of vaccine products		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Interchange of vaccine products		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ASTHMA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Asthma		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Asthma		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRODUCT DOSE OMISSION ISSUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Product dose omission issue		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Product dose omission issue		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a Non-Interventional Study report from a contactable Other Health Professional. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report No E2B_04459575. (Linked Regulatory No E2B_03809929). This information was initially reported to Health Canada between 23Jul2021 and 28Jul2021 from an unknown Market Authorization Holder AER# CA2021AMR157705.

A 56-year-old female patient received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation; BNT162b2 (BNT162B2), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation; BNT162b2 (COMIRNATY), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation; chadox1 ncov-19 (CHADOX1 NCOV-19), as dose number unknown, single (Batch/Lot number: unknown) intramuscular for covid-19 immunisation; mepolizumab (MEPOLIZUMAB), (Batch/Lot number: unknown) at 100 mg, subcutaneous for asthma. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: INTERCHANGE OF VACCINE PRODUCTS (death), outcome "fatal", described as "Covid-19 vaccine/Chadox"; ASTHMA (death), outcome "fatal"; PRODUCT DOSE OMISSION ISSUE (death), outcome "fatal". The action taken for mepolizumab was unknown. The patient date of death was unknown. Reported cause of death: "Asthma", "Product dose omission issue". It was not reported if an autopsy was performed.

The reporter's assessment of the causal relationship of all events with the suspect product bnt162b2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (13Dec2022): This is a non-interventional study report received from the same contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: E2B_04459575 (Health Canada). This information was initially reported to Health Canada between 23Jul2021 and 19Aug2022 from an unknown Market Authorization Holder AER# CA2021AMR157705.

Updated information included: new suspect products (BNT162b2 (COMIRNATY), chadox1 ncov-19) and new event (Interchange of vaccine products).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on known drug safety profile, there is reasonable possibility of causal association between the event Asthma (fatal),and Interchange of vaccine products(fatal) and BNT162B2.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
Based on known drug safety profile, there is no reasonable possibility of causal association between the event Product dose omission issue (fatal) and BNT162B2.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Asthma		
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Product dose omission issue		
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)	

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	
		Other studies	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04959596 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211201 CCYYMMDD
	HC Initial Received Date:	20211201 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101604834(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211116 CCYYMMDD	20211116 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101604834

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101604834

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04959596 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML**	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from medical information team.

A patient (no qualifiers provided) received bnt162b2 (COMIRNATY) (Batch/Lot number: unknown) as dose 1, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DEATH (death), outcome "fatal", described as "died". The patient date of death was unknown. The reported cause of death was "Died". It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04965589 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211202 CCYYMMDD
	HC Initial Received Date:	20211202 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101655031(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211124 CCYYMMDD	20211124 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101655031

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CAEPISS PFIZERINC	V2113283 CA-PFIZER INC-202101655031

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			65 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Myocarditis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EW0216	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MYOCARDITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Myocarditis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Myocarditis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from Regulatory Authority. Regulatory number: V2113283 (CAEFISS).

A 65 year-old female patient received bnt162b2 (BNT162B2), administration date [redacted]021 (Lot number: EW0216) as dose 1, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: MYOCARDITIS (death, hospitalization, medically significant), outcome "fatal", described as "Myocarditis". The patient date of death was unknown. The reported cause of death was myocarditis. It was not reported if an autopsy was performed. Impact of Adverse Event Following Immunization (AEFI): prevented daily activities.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myocarditis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Tropiano, Stephano (HC/SC)

From: Canada Vigilance BC (HC/SC)
Sent: 2021-06-16 9:46 AM
To: Canada.Vigilance.NCR-RCN (HC/SC)
Subject: FW: Possible Serious Adverse Effect of mRNA Vaccine

Categories: COVID

Good morning,
Please see email below.
Thanks,
Ausmar

From [redacted]
Sent: 2021-06-16 8:15 AM
To: Canada Vigilance BC (HC/SC) <hc.canada.vigilance.bc.sc@canada.ca>
Cc: [redacted]
Subject: Possible Serious Adverse Effect of mRNA Vaccine

I am writing out of concern for how my mother passed away last week in [redacted] I have not been given much information on the causes because it happened too fast for even the doctors to keep up.

Her name was [redacted] and she passed on [redacted] 2021 in [redacted] hospital. She had gone in the [redacted] before with shortness of breath. They put her in a Covid Unit isolation while they investigated. She had already had the first dose of Pfizer Vaccine. They tested her 3 times for Covid and said they all came back negative. They explained that they were seeing a bunch of spots all over her lungs but had no explanations. Her oxygen was dropping rapidly so they moved her to a lung unit on [redacted] with oxygen. They tested her for everything they could think of from TB, Legionnaires, pneumonia, etc. and found nothing. Bionic antibiotics had no effect on it. She never smoked in her life and was physically walking every day. They began discussions with her sister about nursing home living and I was called on [redacted] to let me know. I wanted to speak to my mother, so a phone was taken back over the hospital, but they were in the process of moving her to palliative care! I never got to speak to her because she died at 1:12 a.m. [redacted] She went down hill extremely fast in 24 hours, and we have no explanation. They did say that maybe it was genetics?

Can I ask that this possibly be investigated, or has it been reported? I realize it is not immediately connected to when she got her vaccine. I am assuming she would have had it a few weeks before that, however I am not sure when she received her vaccine. I am nervous if it is genetic related and vaccine related because I am due to have my second shot and it will be a mix of Astra and Pfizer.

Thank you so much for any help, if any you can provide. I am sending this from my work email, but if you prefer my home contact it is: [redacted]

Sincerely,

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[redacted]

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Canada Vigilance AER#:	E2B_04965594 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220120 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101654785(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211124 CCYYMMDD	20220111 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101654785

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CAEPISS PFIZERINC	V2129701 CA-PFIZER INC-202101654785

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			24 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Myocarditis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

ATIA - 19(1)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)** FA9099	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 2021[redacted] CCYYMM	**Drug end date (B.4.k.14)** 202[redacted] CCYYMM	
Start period (B.4.k.13.1) 80640 Minutes	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19) ExpDT=30-NOV-2021		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Myocarditis	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Myocarditis	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MYOCARDITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Myocarditis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Myocarditis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
80640 Minutes		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non healthcare professional) from Regulatory Authority. The reporter is the patient. Regulatory number: V2129701 (CAEFISS).

An 18 to 29 years (as reported) female patient (unknown if pregnant) received bnt162b2 (BNT162B2), administration date [redacted]2021 (Lot number: FA9099, expiration date: 30Nov2021) as DOSE 2, SINGLE for covid-19 immunization. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (Dose 1, single, Manufacturer Unknown, Date of application unknown), for covid-19 immunization. The following information was reported: MYOCARDITIS (death, hospitalization), outcome "fatal", described as "Myocarditis occurred 80640 minutes after vaccination". The patient date of death was unknown. The reported cause of death was myocarditis. It was unknown if an autopsy was performed.
Conclusion: The complaint for an Adverse Event Safety Request For Investigation from a vial the PFIZER-BIONTECH COVID-19 VACCINE lot FA9099 was investigated. The investigation included a review of manufacturing and packaging batch records, retain samples, deviation investigations, and an analysis of the complaint history for the reported lot. The final scope was determined to be the reported finished goods lot FA9099, fill lot FA9129, and the bulk formulated drug product lot EP8667. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality. No root cause or corrective and preventive actions (CAPA) were identified because the complaint was not confirmed.
No follow-up attempts are possible. No further information expected.

Follow-up (11Jan2022): This is a follow-up report from product quality group providing investigation results. Updated information included: expiration date of lot number FA9099. Investigation results provided.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myocarditis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a) COVID-19 VACCINE	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	Indication (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04965599 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211202 CCYYMMDD
	HC Initial Received Date:	20211202 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101654873(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211124 CCYYMMDD	20211124 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101654873

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CAEPISS PFIZERINC	V2127581 CA-PFIZER INC-202101654873

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			65 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Myopericarditis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Canada Vigilance AER#:	E2B_04965599 (0)	Page#3

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	FA9091	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
4 Days	4 Days	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myopericarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myopericarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MYOPERICARDITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Myopericarditis

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Myopericarditis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
4 Days	4 Days	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from Regulatory Authority. Regulatory number: V2127581 (CAEFISS).

A 65 year-old male patient received bnt162b2 (BNT162B2), administration date [redacted]021 (Lot number: FA9091) as dose 2, single for covid-19 immunisation. Relevant medical history included: "gastrointestinal bleeding" (unspecified if ongoing); "cataract extraction" (unspecified if ongoing); "gout" (unspecified if ongoing); "hypertension" (unspecified if ongoing). The patient's concomitant medications were not reported. Past drug history included: Asa, notes: ASA 81 mg; Rabeprazole. Vaccination history included: Covid-19 vaccine (Dose 1, unknown manufacturer), for COVID-19 immunisation. The following information was reported: MYOCARDITIS (death, medically significant) with onset[redacted]2021, outcome "fatal", described as "Myopericarditis". Therapeutic measures were not taken as a result of myocarditis. The patient date of death was [redacted]021. The reported cause of death was myocarditis. It was not reported if an autopsy was performed. Impact of Adverse Events Following Immunization (AEFI): prevented daily activities.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Gastrointestinal bleeding	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cataract extraction	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Gout	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myopericarditis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)
ASA

Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Drug name (B.1.8a)
COVID-19 VACCINE

Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
26.0	COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Drug name (B.1.8a)
RABEPRAZOLE

Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04970461 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211203 CCYYMMDD
	HC Initial Received Date:	20211203 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-399962(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211126 CCYYMMDD	20211126 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2021-399962

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2021-399962

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			31 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04970461 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04970461 (0)	Page#3
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	1 Days
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEATH (passed away) in a 31-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.

No Medical History information was reported.

On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form.
On an unknown date, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on[redacted]2021 The patient died on[redacted]2021. The cause of death was not reported. It is unknown if an autopsy was performed.

No relevant concomitant and treatment medications were reported.
Patient was doing amazingly well and as soon as he got his first and second dose, his body could not handle it any more and passed away within 2 months of his second shot.

Company comment
This case concerns a 31-year-old male patient with no relevant medical history, who experienced the serious unexpected event of Death. The event occurred on an unknown number of days after receiving the second dose of mRNA-1273 Vaccine with undisclosed vaccination date. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case concerns a 31-year-old male patient with no relevant medical history, who experienced the serious unexpected event of Death. The event occurred on an unknown number of days after receiving the second dose of mRNA-1273 Vaccine with undisclosed vaccination date. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04970461 (0)	Page#5

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04993490 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220118 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101684313(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20211127 CCYYMMDD	20220110 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101684313

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101684313

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04993490 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) for a Pfizer sponsored program (005570).

A male patient received bnt162b2 (COMIRNATY) (Batch/Lot number: unknown) as dose 2, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (Dose 1, MANUFACTURER UNKNOWN), for COVID-19 immunisation.
The following information was reported: DEATH (death), outcome "fatal", described as "death". The patient date of death was unknown. The reported cause of death was "he dropped dead". Clinical course: The consumer stated the 2nd dose of the covid vaccine led to his/her father's death. He dropped dead. The patient left a full medical history on the table with instructions to sue Pfizer explaining how the vaccine affected a certain gene which led to his eventual death. It was not reported if an autopsy was performed.

The lot number for bnt162b2 was not provided and will be requested during follow up.

Follow-up (10Jan2022): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04993490 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a) COVID-19 VACCINE	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	Indication (B.1.8f.2) COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04997896 (4)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221109 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A862455()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211208 CCYYMMDD	20221107 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2) CA-AstraZeneca-2021A862455

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
HEALTH CANADA Market Authorization Holder AER Number MC CANADA AZPROD0000	E2B_04586624 EU-2021-02662 [redacted] CA-AstraZeneca-2021A862455

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (2) , (2) , (2) E2B_05028497

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male	159 Centimeter	63 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			70 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Pneumonia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3) Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown-DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1) 1 Years	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) .5 ml		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	LONSURF	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7) Tablet	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Colorectal cancer metastatic
Start date of drug (B.4.k.12) 2020 CCYY	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1) 1 Years	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No	2021		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
1 Years		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the Health Professional via regulatory authority in Canada (HEALTH CANADA) concerning a male patient of Unknown ethnic origin (age 70 years, height 159 cm, weight 63 kg).

No medical history and concomitant products were reported.

On an unknown date, the patient received Vaxzevria Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number Unknown), via intramuscular route, for covid-19 immunisation. On an unknown date, the patient received Chadox1 Ncov-19 (covid-19 vaccine nrvv ad (chadox1 ncov-19)) 0.5 ml , via intramuscular route, for covid-19 immunisation.

The patient started treatment with Lonsurf (tipiracil hydrochloride, trifluridine), oral, during 2020 for colorectal cancer metastatic.

During 2021, the patient experienced pneumonia (preferred term: Pneumonia).

It was unknown if any action was taken with Chadox1 Ncov-19 and Lonsurf. Action taken with Vaxzevria Vial Contains 10 Doses Of 0.5ml was not applicable.

During 2021, the patient died from the event for pneumonia.

It was not known whether an autopsy was performed. The cause of death was pneumonia.

The reporter assessed the event pneumonia to be serious due to seriousness criterion death and hospitalised.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Summary of follow-up information received by AstraZeneca/MedImmune on 10-Jun-2022 from consumer via Spontaneous source: Action taken updated for both suspects. Start date added for the event, Narrative amended.

Summary of follow up information received by AstraZeneca/MedImmune on 08-Aug-2022 from health professional via spontaneous source: Reporter tab updated. New reporter health professional were added. Reporting verbatim of suspect updated to Covid-19 Vaccine Astrazeneca. suspect indication was updated to covid-19 immunisation. Causality was updated. Action taken with Lonsurf was changed. Lot no added as Unknown. Dosage text were added. Narrative amended.

Summary of follow up information received by AstraZeneca/MedImmune on 05-Sep-2022 from health professional via spontaneous source: New reference reporters added. duplicate case identified. associated changes made. Verbatim of the suspect updated from COVID-19 VACCINE ASTRAZENECA to VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML.Narrative amended.

Summary of follow up information received by AstraZeneca/MedImmune on 07-Nov-2022 from health professional via spontaneous source: Suspect product CHADOX1 NCOV-19 was added, .Narrative amended.CAUSE OF DEATH: PNEUMONIA PNEUMONIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fata event of Pneumonia is not listed in the company core data sheet of AZD1222. The cause of death was reported as Pneumonia. Reported medical history of colorectal cancer metastatic and vaccinee's advance age could be considered as a risk factors for the event. Use of concomitant medication tipiracil hydrochloride, trifluridine could be considered as confounding factor for the event. Due to limited information on details and circumstances surrounding the event, exact date of vaccination, event onset date, concomitant medications, relevant family history, autopsy details, detailed etiological and diagnostic work-up, the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Pneumonia		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	

Comments (B.1.7.1g)

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	HEALTH CANADA

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04998124 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230505 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A863505()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20211208 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20230504 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A863505

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC CANADA Market Authorization Holder AER Number AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_04551664 [redacted] 202101022711 CA-AstraZeneca-2021A863505

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13) Yes	**Reason for nullification (A.1.13.1)** Case is a duplicate of Manufacturer Report Number [CA-AstraZeneca-2021A684767]

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

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Canada Vigilance AER#:	E2B_04998124 (2)	Page#2

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			95 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cardiac failure congestive
MedDRA version for cause (B.1.9.2.a)	**Reported cause(s) (B.1.9.2.b)**
26.0	Dyspnoea

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown- Single		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ELIGARD	
Active Substance names (B.4.k.2.2)		
leuprolide acetate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
22.5 Milligram,1 every 3 (Months)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Prostatic cancer
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CARDIAC FAILURE CONGESTIVE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cardiac failure congestive		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cardiac failure congestive		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSPNOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dyspnoea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer via the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY), concerning a male patient of unknown ethnic origin (age 95 years).

The patient's past and current medical history included prostate cancer (dates not reported), cardiac failure congestive (dates not reported) and dyspnoea (dates not reported).

No concomitant products were reported.

On an unknown date, the patient received Covid-19 Vaccine (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for covid-19 immunisation.

The patient started treatment with Eligard (leuprorelin acetate) 22.5 mg every three months, subcutaneous, on an unknown date for prostate cancer.

On an unknown date, the patient experienced cardiac failure congestive (preferred term: Cardiac failure congestive) and dyspnoea (preferred term: Dyspnoea).

The action taken with dose unknown Covid-19 Vaccine was not applicable. It was unknown if any action was taken with Eligard.

On an unspecified date, the patient died from the event of cardiac failure congestive and dyspnoea.

It was not known whether an autopsy was performed. The cause of death was cardiac failure congestive and dyspnoea.

The reporter assessed the events of cardiac failure congestive and dyspnoea as serious due to seriousness criterion of death.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

This case was marked as suppressed due to Duplicate case.

Summary of follow-up information received by AstraZeneca/MedImmune 10-Jun-2022 from consumer via spontaneous source: Action taken for Covid-19 vaccine updated to not applicable from unknown. Narrative amended. Corrected report on 16-Jun-2022: MAH refer number 202101022711 added. Narrative amended

Minor correction on 14-Jul-2022: Evaluate again on date 01-Jan-0001 removed. Relevant history prostate cancer, dyspnoea, cardiac failure congestive added. Narrative updated.

Summary of follow-up information received by AstraZeneca/MedImmune 04-May-2023 from consumer via spontaneous source: Duplicate case identified. Reporter case id associated. Narrative amendedCAUSE OF DEATH: CARDIAC FAILURE CONGESTIVE CAUSE OF DEATH: DYSPNOEA
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

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MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal events of Cardiac failure congestive and Dyspnoea are not listed in the company core data sheet of AZD1222. The cause of death was described as Cardiac failure congestive and Dyspnoea. Cardiac failure congestive could be considered as a confounding factor for Dyspnoea. Advanced age could be considered as a contributory risk factor for the events. Due to limited information on baseline health condition before vaccination, circumstances leading to the events, concurrent conditions, relevant medical history, family history, date of vaccination, onset date of the events, concomitant medications, risk factors (smoking, alcohol use, obesity, stress, and infection), etiological and complete diagnostic workup (detailed autopsy report), the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Prostate cancer	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac failure congestive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac failure congestive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)
Pharmaceutical Company	AZPROD0000

Department (A.3.1.3a)	Title (A.3.1.3b)
Patient Safety	

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Patient Safety		Interface Organisation

Street (A.3.1.4a)
[redacted]

City (A.3.1.4b)	State (A.3.1.4c)
[redacted]	

Postcode (A.3.1.4d)	Country code (A.3.1.4e)
[redacted]	United Kingdom

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)
[redacted]	[redacted]

Email Address (A.3.1.4l)
Sapphire.BusinessSupport@astrazeneca.com

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Receiver (A.3.2)

Type (A.3.2.1) Regulatory Authority		**Organization** (A.3.2.2a) MHPD
Department (A.3.2.2b) Trading Partner Management Office		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a) 250 Lanark Avenue, Mail Stop 2005A		
City (A.3.2.3b) Ottawa		**State** (A.3.2.3c) ON
Postcode (A.3.2.3d) K1A 0K9		**Country** (A.3.2.3e) Canada
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l) TPMO_BGPC@hc-sc.gc.ca		

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Canada Vigilance AER#:	E2B_05011774 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211217 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-JNJFOC-20211214858(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-JNJFOC-20211214858

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
JNJFOC	CA-JNJFOC-20211214858

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - JANSSEN INC

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1953[redacted] CCYYMMDD	Elderly		69 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)
			[redacted]

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	KLS0H12, KLS0H12	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
520 Milligram,1 every 8 (Weeks)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Crohn's disease
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
49 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable	Unknown	
Additional info (B.4.k.19)		
Provide the reason why sample is not available :: Discarded		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
26.0	Death	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Crohn's disease aggravated	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related

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MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Crohn's disease aggravated	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)** Clinical Judgement	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	
Source of assessment (B.4.k.18.2) Company	**Method of assessment (B.4.k.18.3)** Clinical Judgement	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)** Clinical Judgement	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Gallstones	
Source of assessment (B.4.k.18.2) Company	**Method of assessment (B.4.k.18.3)** Clinical Judgement	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Gallstones	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)** Clinical Judgement	**Result (B.4.k.18.4)** Related

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 prophylaxis
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
49 Days		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FLARE UP OF CROHN'S

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Crohn's disease aggravated		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Crohn's disease		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GALL STONES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Gallstones		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cholelithiasis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This solicited report received from a pharmacist via [redacted] Bio Advance REMICADE SIMPONI STELARA IMBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA concerned a 69 year old female (patient number: [redacted] (local case ID# [redacted].
The patient's height, and weight were not reported. The patient's concurrent conditions included: Crohn's disease.
The patient was treated with ustekinumab (Strength 130 milligram) (solution for infusion, intravenous and batch number: KL50H12 expiry: 30-NOV-2025) 520 mg, 1 time every 8 weeks, from [redacted]021 for Crohn's disease. Non-company suspect vaccine included: covid-19 vaccine (form of admin, route of admin, and batch number were not reported) dose, frequency, and therapy dates were not reported for covid-19 prophylaxis. No concomitant medications were reported.
On an unspecified date in 2021, the patient had gallstone and was going for ultrasound and blood work. Wants to know when the best time would be to get a booster of COVID. Had a flare up of her Crohn's with last COVID vaccine. The family doctor told her to ask us to see what to do about STELARA injection and COVID vaccine -I directed her to the doctors office.
The patient's spouse called to cancel medication since the patient passed away on a day before the day of reporting [redacted]2021). The patient died from unknown cause of death. It was unknown if an autopsy was performed.
The action taken with ustekinumab was not applicable with respect to passed away. The action taken with ustekinumab was not reported with respect to gall stones and flare up of Crohn's, and covid-19 vaccine was not applicable.
The patient died of passed away on [redacted]2021, and the outcome of gall stones and flare up of Crohn's was not reported.
The reporter considered the causality between ustekinumab, and passed away, flare up of Crohn's, and gall stones as related. The reporter did not provide a causality assessment between covid-19 vaccine, and passed away, flare up of Crohn's, and gall stones. Company causality between ustekinumab, and passed away, flare up of Crohn's, and gall stones was not related.
This report was serious (Death, and Other Medically Important Condition).
This case, involving the same patient is linked to 20211052390.

Additional information was received from other health professional (Pharmacist) on [redacted]2021 following information was updated and incorporated into case narrative:- End therapy updated, Additional event(Deceased and related fields), Disease tab(unknown cause of death, date of death, autopsy performed), Case level outcome and seriousness criteria updated, narrative updated, and other identification numbers was added.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

V1: Follow up information updates additional fatal event (deceased) and related fields, disease tab (unknown cause of death, date of death, autopsy performed), case level outcome and seriousness criteria, narrative updated, and other identification numbers.
This case concerns a 69-year-old female patient who experienced flare up of Crohn's after receiving COVID vaccine, unspecified period and later passed away due to unknown reason approximately 1 month after the initiation of Ustekinumab therapy for Crohn's disease. The reported event flare up of Crohn's after receiving COVID vaccine is confounded by patient's underlying disease of Crohn's disease which is chronic in nature, follows a remitting, relapsing path and is prone to progress and flare's, hence company causality assessed as not related.
Available information precludes complete and meaningful medical assessment hence causality of event passed away was assessed as not related

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Crohn's disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
Mrs.	[redacted]		[redacted]

Reporter organization (A.2.1.2a) [redacted] | **Reporter department** (A.2.1.2b)

Reporter street (A.2.1.2c) [redacted]

Reporter city (A.2.1.2d) [redacted] | **Reporter state** (A.2.1.2e) [redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
BioAdvance REMICADE SIMPONI STELARA IMBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA	
Sponsor Study no. (A.2.3.2) [redacted]	**Observed study type** (A.2.3.3) Other studies

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05012072 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221026 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A866513()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20211208 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20221024 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A866513

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) HEALTH CANADA MC CANADA MC CANADA AER NUMBER A2PROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_04594271 [redacted] 202101748284 CA-AstraZeneca-2021A866513

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

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Canada Vigilance AER#:	E2B_05012072 (2)	Page#2

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			49 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Abdominal pain
26.0	Arthralgia
26.0	Death
26.0	Lymphadenopathy
26.0	Pyrexia
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown-DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0 26.0	COVID-19 immunisation COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ALEMTUZUMAB	
Active Substance names (B.4.k.2.2)		
alemtuzumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
12 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
12.0 Milligram; 1 every 1 Days		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous drip	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Relapsing-remitting multiple sclerosis Relapsing-remitting multiple sclerosis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ACRIVASTINE	
Active Substance names (B.4.k.2.2) acrivastine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 50 Milligram		
Dosage text (B.4.k.6) 50.0 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15) 11 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACETAMINOPHEN	
Active Substance names (B.4.k.2.2)		
acetaminophen		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous drip	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ACYCLOVIR SODIUM	
Active Substance names (B.4.k.2.2) acyclovir sodium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 200 Milligram		
Dosage text (B.4.k.6) 200.0 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15) 11 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	FROVATRIPTAN SUCCINATE	
Active Substance names (B.4.k.2.2)		
frovatriptan succinate monohydrate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2.5 Milligram		
Dosage text (B.4.k.6)		
2.5 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	GABAPENTIN	
Active Substance names (B.4.k.2.2)		
gabapentin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
300 Milligram		
Dosage text (B.4.k.6)		
300.0 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	GRAVOL	
Active Substance names (B.4.k.2.2)		
dimenhydrinate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
50 Milligram		
Dosage text (B.4.k.6)		
50.0 Milligram		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METHYLPREDNISOLONE SODIUM SUCCINATE	
Active Substance names (B.4.k.2.2)		
methylprednisolone sodium succinate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Gram		
Dosage text (B.4.k.6)		
1.0 Gram		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MIRTAZAPINE	
Active Substance names (B.4.k.2.2)		
mirtazapine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
45 Milligram		
Dosage text (B.4.k.6)		
45.0 Milligram		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NAPROXEN	
Active Substance names (B.4.k.2.2)		
naproxen		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
500 Milligram		
Dosage text (B.4.k.6)		
500.0 Milligram		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NORTRIPTYLINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
nortriptyline hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
25 Milligram		
Dosage text (B.4.k.6)		
25.0 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) RANITIDINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) ranitidine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 150 Milligram		
Dosage text (B.4.k.6) 150.0 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15) 11 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VENLAFAXINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) venlafaxine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 37.5 Milligram		
Dosage text (B.4.k.6) 37.5 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN B 12 [VITAMIN B12 NOS]	
Active Substance names (B.4.k.2.2) vitamin b12		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN D	
Active Substance names (B.4.k.2.2) vitamin d3		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02505142 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** VITAMIN E NOS	
Active Substance names (B.4.k.2.2) herbals homeopathic		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ZOLMITRIPTAN	
Active Substance names (B.4.k.2.2)		
zolmitriptan		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
5 Milligram		
Dosage text (B.4.k.6)		
5.0 Milligram		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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ABDOMINAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Abdominal pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Abdominal pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ARTHRALGIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Arthralgia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Arthralgia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LYMPHADENOPATHY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lymphadenopathy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Lymphadenopathy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PYREXIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pyrexia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pyrexia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GAIT DISTURBANCE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Gait disturbance		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Gait disturbance		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD PRESSURE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Blood pressure increased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Blood pressure increased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Haemophagocytic lymphohistiocytosis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Haemophagocytic lymphohistiocytosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ATYPICAL PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Atypical pneumonia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Atypical pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHEST PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chest pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Chest pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COUGH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cough
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**

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26.0	Cough		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART RATE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart rate increased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Heart rate increased		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INFLUENZA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Influenza		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Influenza		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NASOPHARYNGITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nasopharyngitis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Nasopharyngitis		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ORAL HERPES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Oral herpes		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Oral herpes		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OROPHARYNGEAL PAIN

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Oropharyngeal pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oropharyngeal pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SINUSITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sinusitis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Sinusitis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VERTIGO

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vertigo
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vertigo

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ALOPECIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Alopecia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Alopecia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RENAL DISORDER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Renal disorder
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Renal disorder

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL PAIN UPPER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Abdominal pain upper		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Abdominal pain upper		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DECREASED APPETITE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Decreased appetite		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Decreased appetite		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIARRHOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Diarrhoea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Diarrhoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HYPERHIDROSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Hyperhidrosis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Hyperhidrosis

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PARAESTHESIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Paraesthesia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Paraesthesia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INFUSION SITE PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Infusion site pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Infusion site pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MALAISE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Malaise
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Malaise

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAIN IN EXTREMITY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pain in extremity
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pain in extremity

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Nausea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Nausea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MIGRAINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Migraine		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Migraine		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ILLNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Illness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Illness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a physician via the regulatory authority in Canada (HEALTH CANADA). The report concerned a female patient of Unknown ethnic origin (age 49 years).

No medical history was reported. Concomitant medication included acrivastine for premedication, paracetamol for premedication, aciclovir sodium for premedication, frovatriptan succinate monohydrate, gabapentin, gabapentin, dimenhydrinate for premedication, methylprednisolone sodium succinate for premedication, mirtazapine, naproxen, nortriptyline hydrochloride, ranitidine hydrochloride for premedication, venlafaxine hydrochloride, vitamin b12 nos, colecalciferol, herbal oil nos and zolmitriptan.

On an unknown date, the patient received unkown single dose of Covid-19 Vaccine Astrazeneca (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number Unknown), via intramuscular route, for covid-19 immunisation. The patient started treatment with Alemtuzumab (alemtuzumab) 12 mg daily, intravenous drip, on an unknown date for relapsing remitting multiple sclerosis and with Alemtuzumab (alemtuzumab) 12 mg daily, intravenous drip, on an unknown date for relapsing remitting multiple sclerosis.

On an unknown date, the patient experienced gait disturbance (preferred term: Gait disturbance), blood pressure increased (preferred term: Blood pressure increased), haemophagocytic lymphohistiocytosis (preferred term: Haemophagocytic lymphohistiocytosis), atypical pneumonia (preferred term: Atypical pneumonia), chest pain (preferred term: Chest pain), cough (preferred term: Cough), heart rate increased (preferred term: Heart rate increased), influenza (preferred term: Influenza), nasopharyngitis (preferred term: Nasopharyngitis), oral herpes (preferred term: Oral herpes), oropharyngeal pain (preferred term: Oropharyngeal pain), sinusitis (preferred term: Sinusitis), vertigo (preferred term: Vertigo), abdominal pain (preferred term: Abdominal pain), arthralgia (preferred term: Arthralgia), lymphadenopathy (preferred term: Lymphadenopathy), pyrexia (preferred term: Pyrexia), alopecia (preferred term: Alopecia), renal disorder (preferred term: Renal disorder), illness (preferred term: Illness), migraine (preferred term: Migraine), pain in extremity (preferred term: Pain in extremity), paraesthesia (preferred term: Paraesthesia), abdominal pain upper (preferred term: Abdominal pain upper), decreased appetite (preferred term: Decreased appetite), diarrhoea (preferred term: Diarrhoea), headache (preferred term: Headache), hyperhidrosis (preferred term: Hyperhidrosis), infusion site pain (preferred term: Infusion site pain), malaise (preferred term: Malaise), nausea (preferred term: Nausea) and death ((preferred term: Death).

Action taken with Covid-19 Vaccine Astrazeneca was not applicable. It was unknown if any action was taken with Alemtuzumab and Alemtuzumab.

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At the time of reporting, the events of gait disturbance, blood pressure increased, haemophagocytic lymphohistiocytosis, atypical pneumonia, chest pain, cough, heart rate increased, influenza, nasopharyngitis, oral herpes, oropharyngeal pain, sinusitis, vertigo, alopecia, renal disorder, abdominal pain upper, decreased appetite, diarrhoea, headache, hyperhidrosis, paraesthesia, infusion site pain, malaise, pain in extremity, nausea, migraine and illness were ongoing. On an unspecified date, the patient died due to abdominal pain, arthralgia, lymphadenopathy, and pyrexia.

It was unknown if autopsy was performed. The cause of death was death, abdominal pain, arthralgia, lymphadenopathy, and pyrexia.

The reporter assessed the events of death, abdominal pain, arthralgia, lymphadenopathy and pyrexia as serious due to seriousness criterion of death. The reporter assessed the events of death, abdominal pain, arthralgia, lymphadenopathy, pyrexia, gait disturbance, blood pressure increased, haemophagocytic lymphohistiocytosis, atypical pneumonia, chest pain, cough, heart rate increased, influenza, nasopharyngitis, oral herpes, oropharyngeal pain, sinusitis, vertigo, alopecia, renal disorder, abdominal pain upper, decreased appetite, diarrhoea, headache, hyperhidrosis, paraesthesia, infusion site pain, malaise, pain in extremity, nausea, migraine and illness as serious due to seriousness criterion of hospitalisation. The reporter assessed the events of death, abdominal pain, arthralgia, lymphadenopathy, pyrexia, gait disturbance, blood pressure increased, haemophagocytic lymphohistiocytosis, atypical pneumonia, chest pain, cough, heart rate increased, influenza, nasopharyngitis, oral herpes, oropharyngeal pain, sinusitis, vertigo, alopecia, renal disorder, abdominal pain upper, decreased appetite, diarrhoea, headache, hyperhidrosis, paraesthesia, infusion site pain, malaise, pain in extremity, nausea, migraine and illness as serious due to seriousness criterion of important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

On an unknown date, the patient underwent the laboratory tests which included blood pressure increased and heart rate increased.

Corrected report on 24-May-2022: The source changed to spontaneous, company causality removed on associated tab and triage tab, the event illness deleted, reference reporters added lot number added as Unknown, duplicate case id associated.

Summary of follow-up information received by AstraZeneca/MedImmune on 24-OCT-2022 from a physician via spontaneous source: Events death, abdominal pain, arthralgia, lymphadenopathy, pyrexia, alopecia, renal disorder, and illness were added. Action taken updated for AZ suspect from Unknown to Not applicable. Death tab updated. Lab tests added. Narrative amended.CAUSE OF DEATH: DEATH CAUSE OF DEATH: ABDOMINAL PAIN CAUSE OF DEATH: ARTHRALGIA CAUSE OF DEATH: LYMPHADENOPATHY CAUSE OF DEATH: PYREXIA CAUSE OF DEATH: UNKNOWN CAUSE OF DEATH DEATH - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ABDOMINAL PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ARTHRALGIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes LYMPHADENOPATHY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PYREXIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes GAIT DISTURBANCE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes BLOOD PRESSURE INCREASED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ATYPICAL PNEUMONIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CHEST PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes COUGH - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HEART RATE INCREASED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes INFLUENZA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NASOPHARYNGITIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ORAL HERPES - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes OROPHARYNGEAL PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes SINUSITIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VERTIGO - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ALOPECIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes RENAL DISORDER - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ABDOMINAL PAIN UPPER - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DECREASED APPETITE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DIARRHOEA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HEADACHE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HYPERHIDROSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PARAESTHESIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes INFUSION SITE PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MALAISE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PAIN IN EXTREMITY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NAUSEA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MIGRAINE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ILLNESS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes Lab Test #1 : 10005727 Lab Test #2 : 10019299
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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This case report concerns a 49 year old female vaccinee with reported fatal outcome (Preferred term: Death) in association with AZD1222. Gait disturbance, Blood pressure increased, Haemophagocytic lymphohistiocytosis, Atypical pneumonia, Chest pain, Cough, Heart rate increased, Influenza, Nasopharyngitis, Oral herpes, Oropharyngeal pain, Sinusitis, Vertigo, Alopecia and Renal disorder are not listed in the company core data sheet of AZD1222. Abdominal pain, Arthralgia, Lymphadenopathy and Pyrexia are listed adverse event for AZD1222, however, since the events were reported with fatal outcome they are considered unlisted. Vaccinee died on an unspecified date and the cause of death was reported as abdominal pain, arthralgia, lymphadenopathy, pyrexia, death and unknown cause of death. Events of Influenza and Nasopharyngitis could be considered as contributory factors to Cough, Oropharyngeal pain and Sinusitis. The event of Atypical pneumonia could be further considered as contributory facctor to Cough and Chest pain. Pyrexia could be also considered as contributory factor to Heart rate increased. Reported relapsing remitting multiple sclerosis could be considered as confounding factor for Gait disturbance. The case is further confounded by polypharmacy. Due to limited information on the exact date of death, onset dates of the events and the vaccine administration, baseline health condition before vaccination, possible risk factors, exact circumstances surrounding the events, clinical course of the events, detailed medical and family history, detailed aetiological and diagnostic workup (results of complete blood analysis, infectious profile, results of pulmonary and cardiological workup including radiology imaging studies), autopsy report with further clarification of the cause of death, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood pressure	Increased	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Heart rate	Increased	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Abdominal pain	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Arthralgia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Lymphadenopathy	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pyrexia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	HEALTH CANADA

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year
	Canada				49	F	??	??	??

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [X] PATIENT DIED
- [X] INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- [ ] INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [X] OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Death (10011906) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Abdominal pain (10000081) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Arthralgia (10003239) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Lymphadenopathy (10025197) [v.26.0] - Fatal
Protocol relatedness:

Cont...

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

1) CHADOX1 NCOV-19(chadox1 ncov-19)(chadox1 ncov-19),Unknown

2) ALEMTUZUMAB(alemtuzumab)(SOLUTION INTRAVENOUS)(alemtuzumab)

Cont...

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)

1) Dose Unknown-DO- 2) 12.0 Milligram;-

16. ROUTE(S) OF ADMINISTRATION

1) Intramuscular 2) Intravenous drip

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATION(S) FOR USE

1) COVID-19 immunisation[10084457] [v.26.0]
COVID-19 immunization[10084464] [v.26.0]

2) Relapsing-remitting multiple sclerosis[10063399] [v.26.0]
Relapsing-remitting multiple

Cont...

18. THERAPY DATES(from/to)

1) 2)

19. THERAPY DURATION

1) 2)

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

ACRIVASTINE(acrivastine)(acrivastine) 50.0 Milligram (50 mg)
ACETAMINOPHEN(acetaminophen)(NOT SPECIFIED)(acetaminophen)

Cont...

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

HealthCanada_Post_Market
Canada

24b. MFR. CONTROL NO.
CA-AstraZeneca-2021A866513
Log No : 2021A866513

24c. DATE RECEIVED BY MANUFACTURER
26/OCT/2022

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
26/OCT/2022

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP

ALEMTUZUMAB

Company Remarks (Sender's comments) :
This case report concerns a 49 year old female vaccinee with reported fatal outcome (Preferred term: Death) in association with AZD1222. Gait disturbance, Blood pressure increased, Haemophagocytic lymphohistiocytosis, Atypical pneumonia, Chest pain, Cough, Heart rate increased, Influenza, Nasopharyngitis, Oral herpes, Oropharyngeal pain, Sinusitis, Vertigo, Alopecia and Renal disorder are not listed in the company core data sheet of AZD1222. Abdominal pain, Arthralgia, Lymphadenopathy and Pyrexia are listed adverse event for AZD1222, however, since the events were reported with fatal outcome they are considered unlisted. Vaccinee died on an

Cont...

Cont... = Continuation attached sheet(s)

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A866513**

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Pyrexia (10037660) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Gait disturbance (10017577) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Blood pressure increased (10005750) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Haemophagocytic lymphohistiocytosis (10071583) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Atypical pneumonia (10003757) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Chest pain (10008479) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Cough (10011224) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Heart rate increased (10019303) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Influenza (10022000) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Nasopharyngitis (10028810) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Oral herpes (10067152) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Oropharyngeal pain (10068319) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Sinusitis (10040753) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Vertigo (10047340) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Alopecia (10001760) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Renal disorder (10038428) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Abdominal pain upper (10000087) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A866513**

Decreased appetite (10061428) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Diarrhoea (10012735) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Headache (10019211) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Hyperhidrosis (10020642) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Paraesthesia (10033775) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Infusion site pain (10053483) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Malaise (10025482) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Pain in extremity (10033425) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Nausea (10028813) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Migraine (10027599) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Illness (10080284) [v.26.0] - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Fatal

A spontaneous report has been received from a physician via the regulatory authority in Canada (HEALTH CANADA). The report concerned a female patient of Unknown ethnic origin (age 49 years).

No medical history was reported. Concomitant medication included acrivastine for premedication, paracetamol for premedication, aciclovir sodium for premedication, frovatriptan succinate monohydrate, gabapentin, gabapentin, dimenhydrinate for premedication, methylprednisolone sodium succinate for premedication, mirtazapine, naproxen, nortriptyline hydrochloride, ranitidine hydrochloride for premedication, venlafaxine hydrochloride, vitamin b12 nos, colecalciferol, herbal oil nos and zolmitriptan.

On an unknown date, the patient received unkown single dose of Covid-19 Vaccine Astrazeneca (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number Unknown), via intramuscular route, for covid-19 immunisation. The patient started treatment with Alemtuzumab (alemtuzumab) 12 mg daily, intravenous drip, on an unknown date for relapsing remitting multiple sclerosis and with Alemtuzumab (alemtuzumab) 12 mg daily, intravenous drip, on an unknown date for relapsing remitting multiple sclerosis.

On an unknown date, the patient experienced gait disturbance (preferred term: Gait disturbance), blood pressure increased (preferred term: Blood pressure increased), haemophagocytic lymphohistiocytosis (preferred term: Haemophagocytic lymphohistiocytosis), atypical pneumonia (preferred term: Atypical pneumonia), chest pain (preferred term: Chest pain), cough (preferred term: Cough), heart rate increased (preferred term: Heart rate increased), influenza (preferred term: Influenza), nasopharyngitis (preferred term: Nasopharyngitis), oral herpes (preferred term: Oral herpes), oropharyngeal pain (preferred term: Oropharyngeal pain), sinusitis (preferred term: Sinusitis), vertigo (preferred term: Vertigo), abdominal pain (preferred term: Abdominal pain), arthralgia (preferred term: Arthralgia), lymphadenopathy (preferred term: Lymphadenopathy), pyrexia (preferred term: Pyrexia), alopecia (preferred term: Alopecia), renal disorder (preferred term: Renal disorder), illness (preferred term: Illness), migraine (preferred term: Migraine), pain in extremity (preferred term: Pain in extremity), paraesthesia (preferred term: Paraesthesia), abdominal pain upper (preferred term: Abdominal pain upper), decreased appetite (preferred term: Decreased appetite), diarrhoea (preferred term: Diarrhoea), headache (preferred term: Headache), hyperhidrosis (preferred term: Hyperhidrosis), infusion site pain (preferred term: Infusion site pain), malaise (preferred term: Malaise), nausea (preferred term: Nausea) and death ((preferred term: Death).

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A866513**

Action taken with Covid-19 Vaccine Astrazeneca was not applicable. It was unknown if any action was taken with Alemtuzumab and Alemtuzumab.

At the time of reporting, the events of gait disturbance, blood pressure increased, haemophagocytic lymphohistiocytosis, atypical pneumonia, chest pain, cough, heart rate increased, influenza, nasopharyngitis, oral herpes, oropharyngeal pain, sinusitis, vertigo, alopecia, renal disorder, abdominal pain upper, decreased appetite, diarrhoea, headache, hyperhidrosis, paraesthesia, infusion site pain, malaise, pain in extremity, nausea, migraine and illness were ongoing. On an unspecified date, the patient died due to abdominal pain, arthralgia, lymphadenopathy, and pyrexia.

It was unknown if autopsy was performed. The cause of death was death, abdominal pain, arthralgia, lymphadenopathy, and pyrexia.

The reporter assessed the events of death, abdominal pain, arthralgia, lymphadenopathy and pyrexia as serious due to seriousness criterion of death. The reporter assessed the events of death, abdominal pain, arthralgia, lymphadenopathy, pyrexia, gait disturbance, blood pressure increased, haemophagocytic lymphohistiocytosis, atypical pneumonia, chest pain, cough, heart rate increased, influenza, nasopharyngitis, oral herpes, oropharyngeal pain, sinusitis, vertigo, alopecia, renal disorder, abdominal pain upper, decreased appetite, diarrhoea, headache, hyperhidrosis, paraesthesia, infusion site pain, malaise, pain in extremity, nausea, migraine and illness as serious due to seriousness criterion of hospitalisation. The reporter assessed the events of death, abdominal pain, arthralgia, lymphadenopathy, pyrexia, gait disturbance, blood pressure increased, haemophagocytic lymphohistiocytosis, atypical pneumonia, chest pain, cough, heart rate increased, influenza, nasopharyngitis, oral herpes, oropharyngeal pain, sinusitis, vertigo, alopecia, renal disorder, abdominal pain upper, decreased appetite, diarrhoea, headache, hyperhidrosis, paraesthesia, infusion site pain, malaise, pain in extremity, nausea, migraine and illness as serious due to seriousness criterion of important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

On an unknown date, the patient underwent the laboratory tests which included blood pressure increased and heart rate increased.

Corrected report on 24-May-2022: The source changed to spontaneous, company causality removed on associated tab and triage tab, the event illness deleted, reference reporters added lot number added as Unknown, duplicate case id associated.

Summary of follow-up information received by AstraZeneca/MedImmune on 24-OCT-2022 from a physician via spontaneous source: Events death, abdominal pain, arthralgia, lymphadenopathy, pyrexia, alopecia, renal disorder, and illness were added. Action taken updated for AZ suspect from Unknown to Not applicable. Death tab updated. Lab tests added. Narrative amended.CAUSE OF DEATH: DEATH CAUSE OF DEATH: ABDOMINAL PAIN CAUSE OF DEATH: ARTHRALGIA CAUSE OF DEATH: LYMPHADENOPATHY CAUSE OF DEATH: PYREXIA CAUSE OF DEATH: UNKNOWN CAUSE OF DEATH DEATH - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ABDOMINAL PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ARTHRALGIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes LYMPHADENOPATHY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PYREXIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes GAIT DISTURBANCE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes BLOOD PRESSURE INCREASED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ATYPICAL PNEUMONIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CHEST PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes COUGH - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HEART RATE INCREASED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes INFLUENZA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NASOPHARYNGITIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ORAL HERPES - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes OROPHARYNGEAL PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes SINUSITIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VERTIGO - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ALOPECIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes RENAL DISORDER - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ABDOMINAL PAIN UPPER - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DECREASED APPETITE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DIARRHOEA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HEADACHE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HYPERHIDROSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PARAESTHESIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes INFUSION SITE PAIN - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MALAISE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PAIN IN EXTREMITY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NAUSEA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MIGRAINE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ILLNESS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes Lab Test #1 : 10005727 Lab Test #2 : 10019299
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Company Remarks (Sender's comments) (Cont...)

unspecified date and the cause of death was reported as abdominal pain, arthralgia, lymphadenopathy, pyrexia, death and unknown cause of death. Events of Influenza and Nasopharyngitis could be considered as contributory factors to Cough, Oropharyngeal pain and Sinusitis. The event of Atypical pneumonia could be further considered as contributory factor to Cough and Chest pain. Pyrexia could be also considered as contributory factor to Heart rate increased. Reported relapsing remitting multiple sclerosis could be considered as confounding factor for Gait disturbance. The case is further confounded by polypharmacy. Due to limited information on the exact date of death, onset dates of the events and the vaccine administration, baseline health condition before vaccination, possible risk factors, exact circumstances surrounding the events, clinical course of the events, detailed medical and family history, detailed aetiological and diagnostic workup (results of complete blood analysis, infectious profile, results of pulmonary and cardiological workup including radiology imaging studies), autopsy report with further clarification of the cause of death, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No.	:	1
Drug	:	CHADOX1 NCOV-19(chadox1 ncov-19)(chadox1 ncov-19),Unknown
Daily Dose	:	1) Dose Unknown-DOSE NUMBER UNKNOWN, SINGLE 2) Dose Unknown-DOSE NUMBER UNKNOWN, SINGLE
Route of Admin	:	1) Intramuscular 2) Intramuscular

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A866513**

Causality

1) Death (10011906) [v.26.0]
Action(s) taken with drug : Not Applicable

Seq.No. : 2
Drug : ALEMTUZUMAB(alemtuzumab)(SOLUTION INTRAVENOUS)(alemtuzumab)
Daily Dose : 1) 12.0 Milligram; 1 every 1 Days (12 mg,1 in 1 D)
2) 12.0 Milligram, 1 every 1 Days (12 mg,1 in 1 D)
Route of Admin : 1) Intravenous drip
2) Intravenous drip
Indication for use : 2) Relapsing-remitting multiple sclerosis[10063399] [v.26.0]

Causality

1) Death (10011906) [v.26.0]
Action(s) taken with drug : Unknown

Concomitant drugs (Cont...)

Seq.No. : 1
Drug : ACRIVASTINE(acrivastine)(acrivastine)
Route of Admin : 1) Oral
Indication for use : 1) Premedication[10036500] [v.26.0]
Therapy Dates/Duration : 1) 11 Days

Seq.No. : 2
Drug : ACETAMINOPHEN(acetaminophen)(NOT SPECIFIED)(acetaminophen)
Route of Admin : 1) Intravenous drip
Indication for use : 1) Premedication[10036500] [v.26.0]
Therapy Dates/Duration : 1) 11 Days

Seq.No. : 3
Drug : ACYCLOVIR SODIUM(acyclovir sodium)(acyclovir sodium)
Daily Dose : 1) 200.0 Milligram (200 mg)
Route of Admin : 1) Oral
Indication for use : 1) Premedication[10036500] [v.26.0]
Therapy Dates/Duration : 1) (11 Days)

Seq.No. : 4
Drug : FROVATRIPTAN SUCCINATE(frovatriptan succinate monohydrate)(frovatriptan succinate monohydrate)
Daily Dose : 1) 2.5 Milligram (2.5 mg)
Route of Admin : 1) Oral

Seq.No. : 5
Drug : GABAPENTIN(gabapentin)(NOT SPECIFIED)(gabapentin)
Daily Dose : 2) 300.0 Milligram (300 mg)
Route of Admin : 1) Unknown
2) Oral

Seq.No. : 6
Drug : GRAVOL(dimenhydrinate)(NOT SPECIFIED)(dimenhydrinate)
Daily Dose : 1) 50.0 Milligram (50 mg)
Route of Admin : 1) Oral
Indication for use : 1) Premedication[10036500] [v.26.0]
Therapy Dates/Duration : 1) (11 Days)

Seq.No. : 7
Drug : METHYLPREDNISOLONE SODIUM SUCCINATE(methylprednisolone sodium succinate)(methylprednisolone sodium succinate)
Daily Dose : 1) 1.0 Gram (1 gm)
Route of Admin : 1) Intravenous (not otherwise specified)
Indication for use : 1) Premedication[10036500] [v.26.0]
Therapy Dates/Duration : 1) (11 Days)

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A866513**

Seq.No. : 8
Drug : MIRTAZAPINE(mirtazapine)(Tablet)(mirtazapine)
Daily Dose : 1) 45.0 Milligram (45 mg)
Route of Admin : 1) Oral

Seq.No. : 9
Drug : NAPROXEN(naproxen)(NOT SPECIFIED)(naproxen)
Daily Dose : 1) 500.0 Milligram (500 mg)
Route of Admin : 1) Oral

DRAFT

Seq.No. : 10
Drug : NORTRIPTYLINE HYDROCHLORIDE(nortriptyline hydrochloride)(nortriptyline hydrochloride)
Daily Dose : 1) 25.0 Milligram (25 mg)
Route of Admin : 1) Oral

Seq.No. : 11
Drug : RANITIDINE HYDROCHLORIDE(ranitidine hydrochloride)(ranitidine hydrochloride)
Daily Dose : 1) 150.0 Milligram (150 mg)
Route of Admin : 1) Oral
Indication for use : 1) Premedication[10036500] [v.26.0]
Therapy Dates/Duration : 1) (11 Days)

Seq.No. : 12
Drug : VENLAFAXINE HYDROCHLORIDE(venlafaxine hydrochloride)(venlafaxine hydrochloride)
Daily Dose : 1) 37.5 Milligram (37.5 mg)
Route of Admin : 1) Oral

Seq.No. : 13
Drug : VITAMIN B 12 [VITAMIN B12 NOS](vitamin b12)(vitamin b12)
Route of Admin : 1) Unknown

DRAFT

Seq.No. : 14
Drug : VITAMIN D(vitamin d3)(Capsules)(vitamin d3)
Route of Admin : 1) Unknown

Seq.No. : 15
Drug : VITAMIN E NOS(herbals homeopathic)(herbals homeopathic)
Route of Admin : 1) Unknown

DRAFT

Seq.No. : 16
Drug : ZOLMITRIPTAN(zolmitriptan)(NOT SPECIFIED)(zolmitriptan)
Daily Dose : 1) 5.0 Milligram (5 mg)
Route of Admin : 1) Oral

Additional information (continuation)

Lab Result :

Test name	Test date	Test result	Normal value	Classification
10005727		Increased		
10019299		Increased		

Initial Reporter (Cont...)

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A866513**

UNKNOWN UNKNOWN HEALTH CANADA
UNKNOWN
UNKNOWN, UNKNOWN UNKNOWN
Canada

DRAFT

DRAFT

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05023524 (3)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220203 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101758319(4)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
2021 [redacted] CCYYMMDD	20220124 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101758319

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101758319

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		

Date of birth (B.1.2.1)	Age group (B.1.2.3)	Onset Age (B.1.2.2)
		27 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05023524 (3)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Myocardial infarct

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20210706 CCYYMMDD	20210706 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of drug administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05023524 (3)	Page#3

MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Inappropriate schedule of drug administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocardial infarct	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocardial infarct	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MYOCARDIAL INFARCT (MI) AND PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Myocardial infarct		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FIRST DOSE: 15MAY2021/ SECOND DOSE:06JUL2021

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Inappropriate schedule of drug administration		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Inappropriate schedule of product administration		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	20210706		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05023524 (3)	Page#4

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Physician) from a sales representative.

A 27-year-old male patient received bnt162b2 (BNT162B2), administration date 06Jul2021 (Batch/Lot number: unknown) as dose 2, single for covid-19 immunization.

The patient's relevant medical history was reported as none and was healthy. Concomitant medications were not reported. Vaccination history included: Bnt162b2 (Dose number: 1, Dose description: Dose 1, single), administration date: 15May2021, for Covid-19. Family medical history relevant to Adverse Event: Health family, Dad, Mom, Brother all alive. Vaccination facility type was Pharmacy or Drug Store.

The following information was reported: MYOCARDIAL INFARCTION (death, medically significant) with onset [redacted]021, outcome "fatal", described as "Myocardial Infarct (MI) and passed away"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (non-serious) with onset 06Jul2021, outcome "unknown", described as "first dose: 15May2021/ Second dose:06Jul2021". The patient date of death was [redacted]2021. Clinical course: A healthy 27-year-old male received the COVID 19 vaccines on 15May and 06July of 2021 and in the latter [redacted]2021, the patient had a Myocardial Infarct (MI) and passed away. The reporter feels that it may be related to the COVID 19 vaccine. The reported cause of death was myocardial infarction. The autopsy was performed, and results were not provided. Comments/ Narrative: I have Known this patient for many years and been his physician. No history for alcohol, drugs and smoking. He was healthy. Normal weight. He has a hardworking model citizen. Only difference between 2020 and 2021 were the 2 Covid vaccines he was taking. The safety of the vaccines are in question.

The lot number for bnt162b2 was not provided and will be requested during follow up.

Follow up [redacted]021): This is a spontaneous follow-up report received via fax from a contactable reporter (Physician): Pfizer/BioNTech COVID-19 Vaccine Follow-up Questionnaire.

Updated information included: Physician information, vaccination facility type, medical history and family medical history, Death Date was updated. Autopsy Done was added. Autopsy result was updated, Start and stop dates were completed for Historical vaccine. Start and stop dates were completed for dosage regimen. New Adverse Event added: Inappropriate schedule of drug administration and clinical information was updated.

Follow-up [redacted]021): New information received from a contactable physician included: It was reported that it may take up to six months to indicate results of autopsy or other postmortem findings.

Follow-up (24Jan2022): This follow-up is being submitted to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the reported information ,a causal relationship between the events and suspected drug cannot be excluded.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myocardial infarct	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

List of non-encoded Patient Relevant History:
Patient Other Relevant History 1: none, Comment: and was healthy

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Canada Vigilance AER#:	E2B_05023524 (3)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a) BNT162B2	
Start date (B.1.8c) 20210515 CCYYMMDD	**End date** (B.1.8e) 20210515 CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	**DOB of Parent** (B.1.10.2.1)	**Age** (B.1.10.2.2)	**LMP date** (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	**Medical history** (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b)	**Reporter middle name** (A.2.1.1c)	**Reporter family name** (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada		**Qualification** (A.2.1.4) Physician
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05028493 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211217 CCYYMMDD
	HC Initial Received Date:	20211217 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101746393(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211207 CCYYMMDD	20211207 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101746393

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101746393

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			34 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05028493 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Myocarditis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	FA9099	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2658 Hours	2658 Hours	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05028493 (0)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LYMPHOHISTIOCYTIC MYOCARDITIS RESULTING IN SUDDEN DEATH AT AGE 34.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Myocarditis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Myocarditis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
2658 Hours	2658 Hours	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter (Consumer). The reporter is the patient.

A 34 year-old male patient received bnt162b2 (BNT162B2), administration date [redacted]2021 (Lot number: FA9099) at the age of 34 years as dose 2, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Bnt162b2 (Dose Number: 1, Batch/Lot No: EW0221, Location of injection: Arm Left), for COVID-19 Immunization.
The following information was reported: MYOCARDITIS (death) with onset [redacted]2021 18:00, outcome "fatal", described as "Lymphohistiocytic myocarditis resulting in sudden death at age 34.". The event "lymphohistiocytic myocarditis resulting in sudden death at age 34." was evaluated at the emergency room visit. The patient underwent the following laboratory tests and procedures: sars-cov-2 test: unknown results. Therapeutic measures were not taken as a result of myocarditis. The patient date of death was [redacted]2021. The reported cause of death was myocarditis. It was not reported if an autopsy was performed.

Additional information: The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine: Prior to vaccination, the patient was not diagnosed with COVID-19.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
	COVID-19 virus test	Unknown results

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myocarditis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a) BNT162B2	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	Indication (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	000954882 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210617 CCYYMMDD
	HC Initial Received Date:	20210617 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR_H-20210617111026_7382()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021 CCYY	2021 CCYY	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male		406 Pound
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			79 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	

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Canada Vigilance AER#:	000954882 (0)	Page#2

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMM	202[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CELLULITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cellulitis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cellulitis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	6 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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Canada Vigilance AER#:	000954882 (0)	Page#4

Summary (B.5)

Case narrative (B.5.1)

patient had numerous severe and palliative comorbid conditions and was on numerous prescription medications

---

Dhpr log details:
Safety Report ID: CA-DHPR_H-Z0210617111026_7382
Type of Report: Initial
HC Ref. No:
Reporter File No.: [redacted]
Transmission Date: 20210617
Documentation Date: 20210607
First Name: [redacted]
Last Name:
Telephone:
Ext.:
Address:
City:
Province/Territory:
Postal Code:
Email address: [redacted]
Organization:
HC ID: [redacted]
Reporter Type: Physician

Patient ID: [redacted]
Age: 79 Year(s)
Sex: Male
Height:
Weight: 406 lbs oz
Med History: Congestive cardiac failure, diabetes mellitus, advanced low-grade follicular lymphoma, multiple myeloma, early stage sigmoid adeno carcinoma, retroperitoneal lymphadenopathy, palliative radiotherapy to SI joint, oral palliative chemotherapy varicose veins, cardiac dysrhythmia, morbid obesity
Allergies: None known

Serious Death: Yes
Date of Death: 2021[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization: Yes
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Died
Reaction Start Date: 2021[redacted]
Reaction End Date: 2021[redacted]
Reaction Description: Patient admitted with cellulitis of the left arm, treated in hospital with IV antibiotics, deceased 1 week after receiving 2nd dose of COVID vaccine Pfizer

Suspect Product 1
DIN #/NPN #:
UPHN #:
Brand Name: Pfizer Vaccine
Common Name:
Strength:
Strength other:
Dosage form:
Manufacturer: Pfizer
Lot #:
Expiry date:
Product start date: 2021[redacted]
Product end date: 2021[redacted]
Dosage:
Dosage other:
Frequency:
Route of administration: Intramuscular
Route of administration - Other:
Indication: vaccine
Reported to Mfr: No
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Not applicable
Dechallenge:
Rechallenge: Unknown

Concomitants:
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congestive cardiac failure	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes mellitus	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Follicular lymphoma	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Multiple myeloma	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Adenocarcinoma of sigmoid colon	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Retroperitoneal lymphadenopathy	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Radiotherapy to joint	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Palliative care	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chemotherapy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Varicose veins	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac dysrhythmias	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Morbid obesity	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Congestive cardiac failure, diabetes mellitus, advanced low-grade follicular lymphoma, multiple myeloma, early stage sigmoid adeno carcinoma, retroperitoneal lymphadenopathy, palliative radiotherapy to SI joint, oral palliative chemotherapy varicose veins, cardiac dysrhythmia, morbid obesity
Allergies:None known

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) [redacted]	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) [redacted]
Reporter organization (A.2.1.2a) [redacted]		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Canada Vigilance AER#:	000954882 (0)	

Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05028497 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211217 CCYYMMDD
	HC Initial Received Date:	20211217 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101746598(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211208 CCYYMMDD	20211208 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101746598

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_04586624 EU-2021-02662 CA-PFIZER INC-202101746598

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_04997896, (1) E2B_04586624

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male	159 Centimeter	63 Kilogram
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			70 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Pneumonia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pneumonia	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	LONSURF	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7) Tablet	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Colorectal cancer metastatic
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a non-interventional study report from Regulatory Authority. Regulatory number: E2B_04586624 (Health Canada). Other Case identifier(s): EU-2021-02662 (Unknown MAH). This is a report received from the Health Canada Regulatory Authority via an on-line database search. This information was initially reported to Health Canada on 24Aug2021 from an unknown Market Authorization Holder AER# EU-2021-02662.

A 70 year-old male patient received BNT162B2 (COVID-19 Vaccine - Manufacturer Unknown), intramuscular (Batch/Lot number: unknown) as dose number unknown, single for covid-19 immunisation; tipiracil hydrochloride, trifluridine (LONSURF), oral (Batch/Lot number: unknown) for colorectal cancer metastatic. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PNEUMONIA (death, hospitalization), outcome "fatal", described as "Pneumonia". The action taken for tipiracil hydrochloride, trifluridine was unknown. The patient date of death was unknown. The reported cause of death was pneumonia. It was unknown if an autopsy was performed.

The reporter's assessment of the causal relationship of the "pneumonia" with the suspect product BNT162B2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

As there is limited information in the case provided, the causal association between the event pneumonia and the vaccine (BNT162B2)cannot be excluded
"The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate."

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pneumonia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Canada Vigilance AER#:	E2B_05028497 (0)	Page#5

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	
	Other studies	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05043181 (4)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221124 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101748284(5)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20211208 CCYYMMDD	20221122 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) CA-PFIZER INC-202101748284

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_04594271 2018SA310104 CA-PFIZER INC-202101748284

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			49 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05043181 (4)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain upper	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Alopecia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Arthralgia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Atypical pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Decreased appetite	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhoea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gait disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Haemophagocytic lymphohistiocytosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hyperhidrosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Illness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Influenza	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Infusion site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lymphadenopathy	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Malaise	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Migraine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nasopharyngitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oral herpes	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oropharyngeal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pain in extremity	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Paraesthesia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pyrexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Renal disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sinusitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vertigo	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ALEMTUZUMAB	
Active Substance names (B.4.k.2.2)		
alemtuzumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
12 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
12 mg, 1x/day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous drip	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Relapsing-remitting multiple sclerosis Relapsing-remitting multiple sclerosis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		3 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ACETAMINOPHEN	
Active Substance names (B.4.k.2.2) acetaminophen		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intravenous drip	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15) 11 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ACYCLOVIR	
Active Substance names (B.4.k.2.2) acyclovir		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 200 Milligram		
Dosage text (B.4.k.6) 200 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15) 11 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	
Active Substance names (B.4.k.2.2) DIPHENHYDRAMINE HYDROCHLORIDE		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 50 Milligram		
Dosage text (B.4.k.6) 50 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Oral	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)** 11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FROVATRIPTAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 2.5 Milligram		
Dosage text (B.4.k.6) 2.5 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** GABAPENTIN	
Active Substance names (B.4.k.2.2) gabapentin		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 300 Milligram		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	GRAVOL	
Active Substance names (B.4.k.2.2)		
dimenhydrinate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
50 Milligram		
Dosage text (B.4.k.6)		
50 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METHYLPREDNISOLONE	
Active Substance names (B.4.k.2.2)		
methylprednisolone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Gram		
Dosage text (B.4.k.6)		
1 g		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
		11 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MIRTAZAPINE	
Active Substance names (B.4.k.2.2)		
mirtazapine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
45 Milligram		
Dosage text (B.4.k.6)		
45 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NAPROXEN	
Active Substance names (B.4.k.2.2)		
naproxen		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
500 Milligram		
Dosage text (B.4.k.6)		
500 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NORTRIPTYLINE	
Active Substance names (B.4.k.2.2) nortriptyline		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 25 Milligram		
Dosage text (B.4.k.6) 25 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) RANITIDINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 150 Milligram		
Dosage text (B.4.k.6) 150 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15) 11 Days
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VENLAFAXINE	
Active Substance names (B.4.k.2.2)		
venlafaxine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
37.5 Milligram		
Dosage text (B.4.k.6)		
37.5 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN B 12 [VITAMIN B12 NOS]	
Active Substance names (B.4.k.2.2)		
vitamin b12		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN D [COLECALCIFEROL]	
Active Substance names (B.4.k.2.2)		
vitamin d3		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** VITAMIN E NOS	
Active Substance names (B.4.k.2.2) vitamin e		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ZOLMITRIPTAN	
Active Substance names (B.4.k.2.2)		
zolmitriptan		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
5 Milligram		
Dosage text (B.4.k.6)		
5 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACRIVASTINE	
Active Substance names (B.4.k.2.2)		
acrivastine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACYCLOVIR SODIUM	
Active Substance names (B.4.k.2.2)		
acyclovir sodium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	FROVATRIPTAN SUCCINATE	
Active Substance names (B.4.k.2.2)		
frovatriptan succinate monohydrate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** METHYLPREDNISOLONE SODIUM SUCCINATE	
Active Substance names (B.4.k.2.2) methylprednisolone sodium succinate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intravenous (not otherwise specified)	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NORTRIPTYLINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
nortriptyline hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) RANITIDINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) ranitidine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VENLAFAXINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL PAIN

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Abdominal pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Abdominal pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ARTHRALGIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Arthralgia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Arthralgia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LYMPHADENOPATHY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Lymphadenopathy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Lymphadenopathy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PYREXIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pyrexia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pyrexia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL PAIN UPPER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Abdominal pain upper
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Abdominal pain upper

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
			3 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ATYPICAL PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Atypical pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Atypical pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD PRESSURE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Blood pressure increased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Blood pressure increased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
			6 Days
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHEST PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Chest pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Chest pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COUGH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cough		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cough		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DECREASED APPETITE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Decreased appetite
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Decreased appetite

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
			3 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIARRHOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Diarrhoea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Diarrhoea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
			6 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GAIT DISTURBANCE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Gait disturbance
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Gait disturbance

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Haemophagocytic lymphohistiocytosis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Haemophagocytic lymphohistiocytosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Headache
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Headache

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
			8 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART RATE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Heart rate increased		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Heart rate increased		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6) 2 Days
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HYPERHIDROSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Hyperhidrosis		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Hyperhidrosis		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6) 3 Days
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INFLUENZA

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Influenza		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Influenza		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INFUSION SITE PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Infusion site pain		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Infusion site pain		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6) 9 Days
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MALAISE

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Malaise		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Malaise		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

MIGRAINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Migraine		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Migraine		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NASOPHARYNGITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nasopharyngitis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Nasopharyngitis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nausea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Nausea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ORAL HERPES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Oral herpes		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Oral herpes		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
			4 Days
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OROPHARYNGEAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Oropharyngeal pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Oropharyngeal pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAIN IN EXTREMITY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pain in extremity
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pain in extremity

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PARAESTHESIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Paraesthesia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Paraesthesia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
			1 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SINUSITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sinusitis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Sinusitis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VERTIGO

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vertigo
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vertigo

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ALOPECIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Alopecia

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MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Alopecia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RENAL DISORDER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Renal disorder		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Renal disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ILLNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Illness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Illness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Summary (B.5)

Case narrative (B.5.1)

NON-INTERVENTIONAL POST-MARKETING STUDY - PROTOCOL TITLE NOT AVAILABLE

This is a non-interventional study report received from a contactable reporter(s) (Physician) from Regulatory Authority. Regulatory number: E2B_04594271 (Health Canada). Other Case identifier(s): 2018SA310104 (Unknown MAH).

A 49-year-old female patient received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) intramuscular for covid-19 immunisation; alemtuzumab (ALEMTUZUMAB), (Batch/Lot number: unknown) for 3 days at 12 mg 1x/day, iv drip for relapsing-remitting multiple sclerosis; alemtuzumab (ALEMTUZUMAB), (Batch/Lot number: unknown) for 2 days at 12 mg 1x/day, iv drip for relapsing-remitting multiple sclerosis; chadox1 ncov-19 (CHADOX1 NCOV-19), (Batch/Lot number: unknown) intramuscular for covid-19 immunisation. The patient's relevant medical history was not reported. Concomitant medication(s) included: ACETAMINOPHEN iv drip taken for premedication; ACYCLOVIR [ACICLOVIR] oral taken for premedication; BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] oral taken for premedication; FROVATRIPTAN oral; GABAPENTIN unknown; GRAVOL oral taken for premedication; METHYLPREDNISOLONE intravenous taken for premedication; MIRTAZAPINE oral; NAPROXEN oral; NORTRIPTYLINE oral; RANITIDINE oral taken for premedication; VENLAFAXINE oral; VITAMIN B 12 [VITAMIN B12 NOS] unknown; VITAMIN D [COLECALCIFEROL] unknown; VITAMIN E NOS unknown; ZOLMITRIPTAN oral; ACRIVASTINE oral taken for premedication; ACYCLOVIR SODIUM oral taken for premedication; FROVATRIPTAN SUCCINATE oral taken for premedication; METHYLPREDNISOLONE SODIUM SUCCINATE intravenous taken for premedication; NORTRIPTYLINE HYDROCHLORIDE oral; RANITIDINE HYDROCHLORIDE oral taken for premedication; VENLAFAXINE HYDROCHLORIDE oral.
The following information was reported: DEATH (death, hospitalization, medically significant), outcome "fatal"; ABDOMINAL PAIN (death, hospitalization, medically significant), outcome "fatal"; ARTHRALGIA (death, hospitalization, medically significant), outcome "fatal"; LYMPHADENOPATHY (death, hospitalization, medically significant), outcome "fatal"; PYREXIA (death, hospitalization, medically significant), outcome "fatal"; ABDOMINAL PAIN UPPER (hospitalization, medically significant), outcome "not recovered"; ATYPICAL PNEUMONIA (hospitalization, medically significant), outcome "not recovered"; BLOOD PRESSURE INCREASED (hospitalization, medically significant), outcome "not recovered"; CHEST PAIN (hospitalization, medically significant), outcome "not recovered"; COUGH (hospitalization, medically significant), outcome "not recovered"; DECREASED APPETITE (hospitalization, medically significant), outcome "not recovered"; DIARRHOEA (hospitalization, medically significant), outcome "not recovered"; GAIT DISTURBANCE (hospitalization, medically significant), outcome "not recovered"; HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (hospitalization, medically significant), outcome "not recovered"; HEADACHE (hospitalization, medically significant), outcome "not recovered"; HEART RATE INCREASED (hospitalization, medically significant), outcome "not recovered"; HYPERHIDROSIS (hospitalization, medically significant), outcome "not recovered"; INFLUENZA (hospitalization, medically significant), outcome "not recovered"; INFUSION SITE PAIN (hospitalization, medically significant), outcome "not recovered"; MALAISE (hospitalization, medically significant), outcome "not recovered"; MIGRAINE (hospitalization, medically significant), outcome "not recovered"; NASOPHARYNGITIS (hospitalization, medically significant), outcome "not recovered"; NAUSEA (hospitalization,

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medically significant), outcome "not recovered"; ORAL HERPES (hospitalization, medically significant), outcome "not recovered"; OROPHARYNGEAL PAIN (hospitalization, medically significant), outcome "not recovered"; PAIN IN EXTREMITY (hospitalization, medically significant), outcome "not recovered"; PARAESTHESIA (hospitalization, medically significant), outcome "not recovered"; SINUSITIS (hospitalization, medically significant), outcome "not recovered"; VERTIGO (hospitalization, medically significant), outcome "not recovered"; ALOPECIA (hospitalization, medically significant), outcome "not recovered"; RENAL DISORDER (hospitalization, medically significant), outcome "not recovered"; ILLNESS (hospitalization, medically significant), outcome "not recovered". The patient underwent the following laboratory tests and procedures: Blood pressure measurement: increased; Heart rate: increased. The action taken for alemtuzumab and alemtuzumab was unknown. The date and cause of death for the patient were unknown.

The reporter's assessment of the causal relationship of "death", "abdominal pain", "arthralgia", "lymphadenopathy", "pyrexia", "abdominal pain upper", "atypical pneumonia", "blood pressure increased", "chest pain", "cough", "decreased appetite", "diarrhoea", "gait disturbance", "haemophagocytic lymphohistiocytosis", "headache", "heart rate increased", "hyperhidrosis", "influenza", "infusion site pain", "malaise", "migraine", "nasopharyngitis", "nausea", "oral herpes", "oropharyngeal pain", "pain in extremity", "paraesthesia", "sinusitis", "vertigo", "alopecia", "renal disorder" and "illness" with the suspect product(s) COVID-19 Vaccine - Manufacturer Unknown was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

Follow up (05Apr2022): This is a follow up non-interventional study report from the same contactable Physician from Regulatory Authority. Regulatory number: E2B_04594271 (Health Canada). Other Case identifier(s): 2018SA310104 (Unknown MAH). This information was initially reported to Health Canada between 25Aug2021 and 03Dec2021 from an unknown Market Authorization Holder AER#2018SA310104. Updated information: new events added: illness, alopecia and renal disorder.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow up (18May2022): This is a follow up non-interventional study report from the same contactable Physician from Regulatory Authority. Regulatory number: E2B_04594271 (Health Canada). Other Case identifier(s): 2018SA310104 (Unknown MAH). This information was initially reported to Health Canada between 25Aug2021 and 07Jan2022 from an unknown Market Authorization Holder AER#2018SA310104. Updated information: new seriousness criteria and event reported: Death.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow up (19Jul2022): New information received from the same contactable Physician as a follow up for this same patient. This is a report received from the HC RA via an on-line database search. Regulatory authority report number E2B_04594271. This information was initially reported to Health Canada between 25Aug2021 and 09Mar2022 from an unknown Market Authorization Holder AER# 2018SA310104. Updated information: new events: Abdominal pain, Arthralgia, Lymphadenopathy and Pyrexia added.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (22Nov2022): This is a report received from the same contactable Physician as a follow up for this same patient. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number E2B_04594271. This information was initially reported to Health Canada between 25Aug2021 and 04Jul2022 from an unknown Market Authorization Holder AER# 2018SA310104. Updated information: Suspect drug details (new suspect products) and new concomitants updated.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on possible temporal association the causal role of BNT162B2 Vaccine cannot be excluded for reported events.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood pressure	increased	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Heart rate	increased	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**

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Canada Vigilance AER#:	E2B_05043181 (4)	Page#40

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
	Other studies

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05124478 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220223 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200020917(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220106 CCYYMMDD	20220214 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200020917

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200020917

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			70 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05124478 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B.4.k.15)**
83 Days	83 Days	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Feeling unwell	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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Canada Vigilance AER#:	E2B_05124478 (1)	Page#3

MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Feeling unwell	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

AND PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
83 Days	83 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MY MOTHER HAD BEEN FEELING UNWELL SINCE HER SECOND DOSE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Feeling unwell		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Malaise		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Allergy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hypersensitivity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

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Canada Vigilance AER#:	E2B_05124478 (1)	Page#4

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP).

A 70 year-old female patient (not pregnant) received bnt162b2 (BNT162B2), administered in arm right, administration date [redacted]2021 (Batch/Lot number: unknown) at the age of 70 years as dose 2, single for covid-19 immunisation. Relevant medical history included: "Deep vein thrombosis" (unspecified if ongoing); "Health problems" (unspecified if ongoing), notes: were all taken care of with proper monitoring and medication. The patient took concomitant medications. Past drug history included: Codiene, reaction(s): "Allergy". Vaccination history included: Bnt162b2 (Dose Number: 1, Batch/Lot No: Unknown. passed away and had been sick since her 2nd dose, Location of injection: Arm Right), for Covid-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine.
The following information was reported: DEATH (death) with onset [redacted]2021, outcome "fatal", described as "and passed away"; MALAISE (death) with onset [redacted]2021, outcome "fatal", described as "My mother had been feeling unwell since her second dose". Therapeutic measures were taken as a result of death, malaise. The patient date of death was [redacted]2021. The reported cause of death was "passed away". It was not reported if an autopsy was performed. Clinical course: My mother had been feeling unwell since her second dose was administered. She called EMS [redacted]2021 and passed away on [redacted]2021. My mom had health problems that were all taken care of with proper monitoring and medication. You killed my mom! Medical treatment was received for palpitations. Prior to vaccination, the patient was not diagnosed with COVID-19; Since the vaccination, the patient has not been tested for COVID-19.

The lot number for bnt162b2 was not provided and will be requested during follow up.

Follow-up (14Feb2022): New information was received to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Deep vein thrombosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	General physical health deterioration	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
were all taken care of with proper monitoring and medication.		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)
BNT162B2

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Drug name (B.1.8a)
CODEINE

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1) v.26.0	**Reaction** (B.1.8g.2) Allergy

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05124481 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220110 CCYYMMDD
	HC Initial Received Date:	20220110 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200018539(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220106 CCYYMMDD	20220106 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200018539

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200018539

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			52 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Booster	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05124481 (0)	Page#3
26.0	Booster	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	Method of assessment (B.4.k.18.3) Global Introspection	Result (B.4.k.18.4) N/A
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	Method of assessment (B.4.k.18.3) Global Introspection	Result (B.4.k.18.4) N/A
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	Method of assessment (B.4.k.18.3) Global Introspection	Result (B.4.k.18.4) N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RECEIVED HIS 3RD INJECTION ''BOOSTER'', ON [redacted]

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Booster		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Immunisation		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

IS UNEXPECTEDLY DEAD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a non-contactable reporter Consumer.

A 52 year-old male patient received BNT162b2 (BNT162B2), administration date [redacted]2021 (Batch/Lot number: unknown) as dose 3 (booster), single for COVID-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: COVID-19 vaccine (Dose 1, MANUFACTUERER UNKNOWN), administration date: [redacted]2021, for COVID-19 immunisation; COVID-19 vaccine (Dose 2, MANUFACTUERER UNKNOWN), for COVID-19 immunisation.
The following information was reported: A 52 year old cardiologist, [redacted] was unexpectedly dead after spending much of 2021 [redacted] The patient received his first mRNA injection on [redacted] He promoted mRNA injections for 12 year olds and made the claim that the shots are undeniably safe. The patient received his 3rd injection booster on [redacted] His last Facebook post was published on [redacted] The patient died on an unspecified date. It was unknown if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)
2021[redacted] CCYYMMDD	202[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0 26.0	COVID-19 immunisation COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05124481 (0)	Page#5

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05139181 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220125 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-JNJFOC-20211158511(5)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) [redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** [redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**	
	Company number (A.1.10.2) CA-JNJFOC-20211158511	

Other case identifiers in previous transmission? (A.1.11) Yes

Duplicate Source(s) (A.1.11.1) JNJFOC	**Duplicate Case identifiers (A.1.11.2)** CA-JNJFOC-20211158511

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) E2B_05135214, (2) E2B_05145139, (2) , (2) , (2) E2B_05135214, (2) E2B_05145139

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4) MAH - JANSSEN INC

Patient (B.1)

Patient Initial (B.1.1) [redacted]	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1) 1940[redacted] CCYYMMDD	**Age group (B.1.2.3)** Elderly		**Onset Age (B.1.2.2)** 81 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)** [redacted]

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05139181 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	KKS1Z07, KKS1Z07, LHS16MC	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
90 Milligram		
Dosage text (B.4.k.6)		
Second dose on [redacted] 2021		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Crohn's disease
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable	Unknown	
Additional info (B.4.k.19)		
Provide the reason why sample is not available :: Discarded		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
26.0	Death	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Itchy rash	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Itchy rash	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shoulder discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shoulder discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
COVID booster on [redacted] 2021		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ITCHY RASH FROM SHOULDER TO ELBOWS AND ACROSS UPPER BACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Itchy rash		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Rash pruritic		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHOULDER DISCOMFORT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Shoulder discomfort		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Musculoskeletal discomfort		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

JOINT PAIN/ SORE SHOULDER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Joint pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Arthralgia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This solicited report received from a health care professional vi[redacted] BioAdvance REMICADE SIMPONI STELARA IMBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA concerned an 81 year old male (patient number: [redacted] (local case ID[redacted].
The patient's height, and weight were not reported. The patient's concurrent conditions included: Crohn's disease. The patient was treated with ustekinumab (solution for injection, subcutaneous, batch number: KKS1Z07 and LHS16MC expiry: UNKNOWN) 90 mg, frequency, and therapy dates were not reported for Crohn's disease. Non-company suspect vaccine included: covid-19 vaccine (form of admin and route of admin were not reported, batch number: UNKNOWN expiry: UNKNOWN) dose, start therapy date were not reported for covid-19 prophylaxis. No concomitant medications were reported.
On[redacted]2021, the patient experienced itchy rash from shoulder to elbows and across upper back, and joint pain/ sore shoulder. On[redacted]2021, the patient experienced shoulder discomfort. On an unspecified date, the patient experienced extremely fatigued, feeling weak, and having some trouble breathing. On[redacted] he went to the hospital and was admitted with pneumonia. He had been transferred to the intensive care unit (ICU) and was now on a ventilator. It was stated that he was tested negative for coronavirus disease (COVID-19). He was currently on intravenous (IV) antibiotics. On[redacted], the patient was died and died from unknown cause of death. It was unknown if an autopsy was performed.
The action taken with ustekinumab was not reported; and action taken with COVID-19 vaccine was not applicable. The action taken with ustekinumab was not applicable with respect to died.
The patient died of died on[redacted] and the outcome of itchy rash from shoulder to elbows and across upper back, joint pain/ sore shoulder, shoulder discomfort and pneumonia was not reported.
The reporter provided no causality assessment. Company causality between ustekinumab, and pneumonia was related, and between ustekinumab, and itchy rash from shoulder to elbows and across upper back, shoulder discomfort, joint pain/ sore shoulder, and died was not related.
This report was serious (Death, and Hospitalization Caused / Prolonged). This case, involving the same patient is linked to 20210210703, 20210720308 and 20220119358.
This case, from the Others is linked to 20220106274.

Additional information was received from other health care professional on[redacted] The following information was updated and incorporated into case narrative: disease (unknown cause of death), additional event(died), narrative updated and other identification numbers.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

V5: Follow up information updates on addition of serious event of died. This information does not alter previous causality assessment of serious event.
This case concerns a 81 year old male patient who was hospitalized for pneumonia manifested as having some trouble breathing, feeling weak and extremely fatigue for which received unspecified intravenous antibiotics and also reported patient died with unknown cause, unspecified duration after the initiation of ustekinumab therapy for Crohn's disease. Considering scientific plausibility to increase risk of infection due to immunomodulating nature properties of ustekinumab, causality was assessed as related with ustekinumab. Based on the available information, a reasonable possibility to suggest a relationship between the drug and the event died cannot be established, hence causality assessed as not related.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
[redacted] CCYYMM	COVID-19 virus test	negative

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
negative			

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Crohn's disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c) | End date (B.1.8e)

Indication MedDRA version (B.1.8f.1) | Indication (B.1.8f.2)

Reaction MedDRA version (B.1.8g.1) | Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1) | DOB of Parent (B.1.10.2.1) | Age (B.1.10.2.2) | LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4) | Height (cm) (B.1.10.5) | Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1) | Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c) | Continuing (B.1.10.7.1d) | End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c) | Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1) | Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1) | Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a) | Reporter given name (A.2.1.1b) [redacted] | Reporter middle name (A.2.1.1c) | Reporter family name (A.2.1.1d) [redacted]

Reporter organization (A.2.1.2a) [redacted] | Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c) [redacted]

Reporter city (A.2.1.2d) | Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f) | Reporter country (A.2.1.3) Canada | Qualification (A.2.1.4) Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1) BioAdvance REMICADE SIMPONI STELARA IMBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA | Project No

Sponsor Study no. (A.2.3.2) [redacted] | Observed study type (A.2.3.3) Other studies

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220308 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200079586(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200079586

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200079586

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			85 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Drug ineffective
26.0	Suspected COVID-19

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Suspected COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Suspected COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19 INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug ineffective		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug ineffective		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2022[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19 INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Suspected COVID-19		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Suspected COVID-19		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from product quality group.

An 85 year-old male patient received bnt162b2 (COMIRNATY), intramuscular (Batch/Lot number: unknown) as dose 3 (booster), single, (Batch/Lot number: unknown) as dose 2, single and (Batch/Lot number: unknown) as dose 1, single for covid-19 immunisation. Relevant medical history included: "Parkinson" (unspecified if ongoing); "terminal rectal cancer" (unspecified if ongoing). The patient's concomitant medications were not reported. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. It was unknown if the patient received any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. It was not known if the patient had allergies.
The following information was reported: DRUG INEFFECTIVE (death, medically significant), SUSPECTED COVID-19 (death, medically significant) all with onset [redacted]2022, outcome "fatal" and all described as "COVID-19 infection". The patient underwent the following laboratory tests and procedures: sars-cov-2 test: unknown result, notes: Since the vaccination, the patient has been tested for COVID-19. Therapeutic measures were taken as a result of drug ineffective, suspected covid-19 included oxygen therapy. The patient date of death was [redacted]2022 at 6:30 PM. The reported cause of death was drug ineffective, suspected covid-19. It was not reported if an autopsy was performed.

Product Quality Group provided investigational results on [redacted]2022 for bnt162b2: Comirnaty (lot: unknown, expiration date: unknown). Brief complaint description: Patient received 3 doses of Pfizer-Biontech vaccine. COVID-19 infection around 1 week prior to today, received oxygen therapy, death on [redacted] at 6:30 PM; Reasonably Suggest Device Malfunction? COVID-19 infection; Severity of Harm: death on Dec15th at 6:30 PM; Complaint Class: Product Use Attributes; Complaint Sub-Class: Lack Of Effect. Root Cause: Not provided Process Related: Not provided; Final Confirmation Status: Not provided; Vendor Related: not provided; Lot-Specific Trend Identified: Not provided; Lot Trend Assmt. & Rationale: Not provided; Lot Trend Actions Taken: Not provided; Other Trend Identified?:Not provided; Other Trend Assmt. & Rationale: Not provided; Site Sample Status: Not provided Summary of Investigation from Product Quality Complaints division was: nor provided ; Investigational report conclusion from Product Quality Complaints division was: not provided.

The lot number for bnt162b2 was not provided and will be requested during follow up.

Follow-up [redacted]2022) This is a follow-up report from product quality group providing investigation results. Updated information included: Investigational results.

The lot number for bnt162b2 was not provided and will be requested during follow up.

Follow-up [redacted]2022): This follow-up is being submitted to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	COVID-19 virus test	Unknown result	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes

Results of tests and procedures (B.3.2)

SARS-CoV-2 test():Since the vaccination, the patient has been tested for COVID-19.

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Parkinson's disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Rectal cancer	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Suspected COVID-19	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug ineffective	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05168152 (2)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05213113 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220201 CCYYMMDD
	HC Initial Received Date:	20220201 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200129737(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220120 CCYYMMDD	20220120 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200129737

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200129737

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05213113 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP).

A female patient received bnt162b2 (COMIRNATY) (Batch/Lot number: unknown) as dose number unknown, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DEATH (death), outcome "fatal", described as "passed away". The patient date of death was unknown. The reported cause of death was "passed away". It was not reported if an autopsy was performed.
The lot number for bnt162b2 was not provided and will be requested during follow up.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

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Canada Vigilance AER#:	E2B_05213113 (0)	Page#5

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05213125 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220214 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200129597(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	Yes
20220120 CCYYMMDD	20220201 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200129597

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200129597

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			75 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

ATIA - 19(1)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Stroke

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	E40578	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
3276 Hours	3276 Hours	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Loss of consciousness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Loss of consciousness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Respiratory disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Respiratory disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) **Current reaction**

STROKE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)
26.0	Stroke
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Cerebrovascular accident

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2021[redacted]			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
3276 Hours	3276 Hours	Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOSS OF CONSCIOUSNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Loss of consciousness
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Loss of consciousness

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2021			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Unknown		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RESPIRATORY DISORDER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Respiratory disorder
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Respiratory disorder

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2021			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Unknown		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Abdominal pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Abdominal pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2021			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Unknown		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Headache
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Headache

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2021			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Unknown		

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP and Physician).

A 75 year-old male patient received bnt162b2 (COMIRNATY), intramuscular, administered in arm left, administration date [redacted]2021 11:45 (Lot number: E40578) at the age of 75 as dose 2, single for covid-19 immunisation. Relevant medical history included: "respiratory problems" (unspecified if ongoing); "Slight emphysema" (ongoing), notes: since a few years. There were no concomitant medications. Vaccination history included: Bnt162b2 (Dose Number: 1, Batch/Lot No: ER1742, Location of injection: Arm Left, Patient Route of Administration : Intramuscular), administration date: [redacted]2021, for covid-19 immunisation.
The following information was reported: CEREBROVASCULAR ACCIDENT (death, disability, hospitalization) with onset [redacted]2021, outcome "fatal", described as "stroke"; LOSS OF CONSCIOUSNESS (medically significant) with onset 2021, outcome "unknown", described as "loss of consciousness"; RESPIRATORY DISORDER (non-serious) with onset 2021, outcome "unknown", described as "respiratory disorder"; ABDOMINAL PAIN (non-serious) with onset 2021, outcome "unknown", described as "abdominal pain"; HEADACHE (non-serious) with onset 2021, outcome "unknown", described as "headaches". The patient was hospitalized for cerebrovascular accident (start date: [redacted]021, discharge date: [redacted]2021, hospitalization duration: 13 day(s)). Therapeutic measures were taken as a result of cerebrovascular accident. The patient date of death was [redacted]2021. The reported cause of death was cerebrovascular accident. No autopsy was performed. Additional information: Following the 2nd dose, my father had loss of consciousness, respiratory disorder, abdominal pain, headaches. Triple cerebrovascular accident with hospitalization on [redacted]2021, transferred to another hospital then died on [redacted]2021 at 07:45am. A hospital document signed by a contactable physician included the following information: Diagnosis: Left sylvian stroke secondary to occlusion "cTG", focal crisis secondary to stroke. The disability is related to a disease. Treatment: intravenous thrombolysis, Acetyl Salicylic Acid, Plavix Keppra. Surgery: Thrombolysis on [redacted]021, Thrombectomy/aspiration and stent of the right internal carotid artery on [redacted]2021.AE required visit to intensive care unit.

Follow-up (01Feb2022): This is a follow-up report from the same contactable consumer and physician. Updated information: Additional Reporter, Patient information, Relevant medical history, Suspect Product data. New events of Loss of consciousness, Respiratory disorder, Abdominal pain, Headache added.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The Company cannot completely exclude the possible causality between the reported fatal stroke, loss of consciousness and the administration of the COVID 19 vaccine, BNT162B2, based on the reasonable temporal association.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Respiratory disorder NOS	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Emphysema	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		
since a few years		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Stroke

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

BNT162B2

Start date (B.1.8c)	End date (B.1.8e)
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
26.0	COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3)	**Qualification** (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3)	**Qualification** (A.2.1.4)	
	Canada	Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		**Title** (A.3.1.3b)
Given name (A.3.1.3c)	**Middle name** (A.3.1.3d)	**Family name** (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		**State** (A.3.1.4c)
Postcode (A.3.1.4d)		**Country code** (A.3.1.4e)
Tel No. (A.3.1.4f)		**Fax no.** (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05216490 (0)		Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220202 CCYYMMDD	
	HC Initial Received Date:	20220202 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A051564()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220131 CCYYMMDD	20220131 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	Company number (A.1.10.2)
	CA-AstraZeneca-2022A051564

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC Canada AZPROD0000	000969583 [redacted] CA-AstraZeneca-2022A051564

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Dyspnoea

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSPNOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Dyspnoea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Dyspnoea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via Consumer. The report concerned a patient of unknown gender (age not provided) of Unknown ethnic origin.

No medical history was reported. No concomitant products were reported.

The patient received an unknown dose of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, on an unknown date. On an unknown date, the patient experienced dyspnoea (preferred term: Dyspnoea).

The action taken with suspect Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable. The patient died from the event on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was dyspnoea.

The event dyspnoea was considered serious due to seriousness criteria death.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.CAUSE OF DEATH: DYSPNOEA
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal outcome of Dyspnoea is not listed in the company core data sheet for AZD1222.
The reported cause of death is Dyspnoea.
Due to limited information on the baseline health characteristics of the patient before vaccination and further clarification of the event, circumstances leading to the event, relevant medical and family history of the patient, concurrent diseases (Cardiovascular disease, Pulmonary disease, Hypertension, Autoimmune disease, Degenerative disease), concomitant medications, specific risk factors (lifestyle, diet, stress, smoker, alcohol consumption), etiological and complete diagnostic work-up (Cardiac biomarkers, immunoglobulin titer, blood chemistry, post-mortem autopsy), the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)		
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)	

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05298714 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220223 CCYYMMDD
	HC Initial Received Date:	20220223 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200268571(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220214 CCYYMMDD	20220214 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200268571

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200268571

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05298714 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FRIEND WHO PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from medical information team.

A male patient received bnt162b2 (COMIRNATY) (Batch/Lot number: unknown) as dose number unknown (booster), single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE NUMBER X, MANUFACTRURER UNKNOWN), for COVID-19 Immunization. The following information was reported: DEATH (death, medically significant), outcome "fatal", described as "friend who passed away". The patient date of death was unknown. The reported cause of death was "friend who passed away". It was not reported if an autopsy was performed. Clinical course: Reporter said she had Covid before and has not been vaccinated. She was being required to be vaccinated was she wants to travel out of the country. She has gone to 3 different pharmacies to ask for information on the possible side effects of the Pfizer Covid Vaccine, each time she was told she could not be provided that information and she should contact Pfizer. She said normally with a medication you get a data sheet with 6-12 years worth of data on complications and complication risk. She asked why does Pfizer not provide this information. She asked why does Pfizer mandate this vaccine. Reporter said she recently had a friend who passed away after getting the Pfizer Covid Vaccine booster dose and prior to the vaccination he was healthy as a horse. She also states that her ex experienced something like bells palsy after getting the vaccine but he was now almost recovered. She asked why are people being forced, in order to travel, to put something in their bodies and then have no legal recourse if it causes them harm.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a) COVID-19 VACCINE	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	Indication (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	000956611 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210720 CCYYMMDD
	HC Initial Received Date:	20210629 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR-20210629145655_140254()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
		Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

Community -

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male		
Date of birth (B.1.2.1)	**Age group** (B.1.2.3)		**Onset Age** (B.1.2.2)
			32 Years
Gestation Period (B.1.2.2.1)		**LMP date** (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

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Patient death cause (B.1.9.2)	
MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)	
MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Canada Vigilance AER#:	000956611 (1)	Page#3

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUDDEN COLLAPSE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Circulatory collapse		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Circulatory collapse		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DROWNING DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drowning		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Drowning		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	

Summary (B.5)

Case narrative (B.5.1)

null

Dhpr log details:
Safety Report ID: CA-DHPR-20210629145655_140254
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20210629
First Name: [redacted]
Last Name:
Telephone:
Ext.:
Address:
City:
Province/Territory:
Postal Code:
Email address:
Organization:
Reporter Type: Consumer or other non health professional

Patient ID: [redacted]
Age: 31 Year(s)
Sex: Male
Height:
Weight:

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ATIA - 19(1)

Med History: N/A
young and healthy active lifestyle
Allergies: unknown

Serious Death: Yes
Date of Death: 202[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Died
Reaction Start Date: 202[redacted]
Reaction End Date: 2021[redacted]
Reaction Description: Sudden collapse and/or heart attack and/or other
Happened while swimming - caused a drowning death
Not sure of exact info (which vaccine, etc)

Suapect Product 1
DIN #/NPN #: Covid19 Vaccine
Product Name: Covid19 Vaccine
Strength:
Strength other:
Dosage form:
Manufacturer:
Lot #:
Expiry date:
Product start date:
Product end date:
Dose:
Frequency:
Route of administration:
Route of administration - Other:
Indication:
Reported to Mfr:
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Unknown
Dechallenge: Unknown
Rechallenge: Unknown

Concomitants:
Test/Lab results narrative:null

Dhpr log details:
Safety Report ID: CA-DHPR-20210629145655_140254
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20210629
First Name:[redacted]
Last Name:
Telephone:
Ext.:
Address:[redacted]
City:
Province/Territory:[redacted]
Postal Code:
Email address:[redacted]
Organization:
Reporter Type: Consumer or other non health professional

Patient ID:[redacted]
Age: 31 Year(s)
Sex: Male
Height:
Weight:
Med History: N/A
young and healthy active lifestyle
Allergies: unknown

Serious Death: Yes
Date of Death: 2021[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Died
Reaction Start Date: 2021[redacted]

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Canada Vigilance AER#:	000956611 (1)	Page#5

Reaction End Date: 2021[redacted]
Reaction Description: Sudden collapse and/or heart attack and/or other
Happened while swimming - caused a drowning death
Not sure of exact info (which vaccine, etc)

Suspect Product 1
DIN #/NPN #: Covid19 Vaccine
Product Name: Covid19 Vaccine
Strength:
Strength other:
Dosage form:
Manufacturer:
Lot #:
Expiry date:
Product start date:
Product end date:
Dose:
Frequency:
Route of administration:
Route of administration - Other:
Indication:
Reported to Mfr:
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Unknown
Dechallenge: Unknown
Rechallenge: Unknown

Concomitants:
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Canada Vigilance AER#:	000956611 (1)	Page#6

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) [redacted]	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) [redacted]
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) [redacted]			
Reporter city (A.2.1.2d) [redacted]		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f) [redacted]	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	000956611 (1)	Page#7

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

It is impossible for me to know if the vaccine had zero, minor, or a major effect in the event. There is reason to at least inquire if the vaccine played a role in the event as the US FDA and health officials in other countries have issued warnings for heart damage (sometimes resulting in failure), particularly in young men, and to avoid exercise for 48 hour minimum following the vaccine, and studies showing such damage and adverse events may take weeks to develop.

The event was sudden heart failure during exercise, with no known previous heart health conditions.

It aggravates me is that i submitted a report, 20210629145655_140254, and then a followup email, but have received received zero communication that this was being followed up on. What gives? Another young man i know was hospitalized for sudden serious heart problems within hours of second vaccine shot, and another died in a similar circumstance to this event, so forgive me for seeing a possible pattern.

Dhpr log details:
Safety Report ID: CA-DHPR-20210720114746_589356
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20210720
First Name: [redacted]
Last Name:
Telephone:
Ext.:
Address: [redacted]
City: [redacted]
Province/Territory [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization:
Reporter Type: Consumer or other non health professional

Patient ID: [redacted]
Age: 32 Year(s)
Sex: Male
Height:
Weight:
Med History: n/a
Allergies: unknown

Serious Death: Yes
Date of Death: 2021[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:

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Serious Other Explain:

Reaction 1
Outcome:
Reaction Start Date:
Reaction End Date:
Reaction Description: undiagnosed heart failure

Suspect Product 1
DIN #/NPN #: unknown
Product Name: covid-19 vaccine
Strength:
Strength other:
Dosage form:
Manufacturer:
Lot #:
Expiry date:
Product start date:
Product end date:
Dose:
Frequency:
Route of administration:
Route of administration - Other:
Indication:
Reported to Mfr:
Date reported to Mfr:
Mfr Reference number:
Drug action taken:
Dechallenge:
Rechallenge:

Concomitants:
Test/Lab results narrative:

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Health Canada / Santé Canada

ATIA - 19(1)

Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Tunney's Pasture AL: 1908C
Ottawa, ON K1A 0K9
Tel (toll-free): 1-866-234-2345
Fax (toll-free): 1-866-678-6789
HC.Canada.Vigilance.SC@canada.ca

[redacted]

July 22, 2021

Re: Side Effect Number 000956611

Dear [redacted]

Thank you for submitting a side effect report to the Canada Vigilance Program (CVP) on June 29, 2021, regarding COVID-19 vaccine. We would like to express our deepest sympathy for your loss and understand that this must be a difficult situation for you. We appreciate the time you took to write about this tragic event and hope that we will be able to address your concerns.

The information that you included in your report has been recorded in the CVP database and assigned the Side Effect Number 000956611. Please reference this number should you wish to report additional information on this event. Please note that Health Canada will contact you about your report only if additional information is required for its surveillance activities.

Regarding your concerns about links between COVID-19 vaccines and heart damage, please note that Health Canada, the Public Health Agency of Canada, the provinces and territories, and manufacturers continue to closely monitor this topic.

In particular, there have been reports associating COVID-19 vaccines with myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining around the heart).

For further information, please visit the Reported side effects following COVID-19 vaccination in Canada paying attention to the highlighted subtitle,

On this page

- What you need to know
- Definitions
- How to report an adverse event
- Summary of adverse event following immunization reports
- Adverse event following immunization reports by vaccine name
- Adverse event following immunization reports by age and sex
- Serious and non-serious adverse events reported
- Adverse events of special interest
- Data notes

Based on these very rare reports, and on other sources of information, Health Canada has updated the product monographs (labels) for the Pfizer-BioNTech and Moderna COVID-19 vaccines. Please visit the safety alert for further information.

The CVP is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products submitted by health professionals and consumers, who report voluntarily, and by manufacturers, distributors and hospitals, who are required to submit reports under the Food and Drugs Act.

Post-market surveillance enables Health Canada to monitor the safety of health products once marketed, to ensure that their benefits continue to outweigh their potential risks, and to take appropriate action to minimize new

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risks. Such actions may include updating the label of a health product, risk communication to inform Canadians of new adverse reactions through safety alerts and/or product recall.

The information from side effect reports as well as information from other sources of data is used to determine whether the benefits of a given health product continue to outweigh its risks.

If you would like to be kept informed of Health Canada's advisories, recalls and other communication on health products, you may subscribe to MedEffect at: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/stay-informed-medeffect-canada.html.

Once again, we would like to extend our sincere condolences, and wish you the best. Please do not hesitate to contact the program if you need further information.

Canada Vigilance Program
Marketed Health Products Directorate
Health Canada

Canada

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05301736 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220224 CCYYMMDD
	HC Initial Received Date:	20220224 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-JNJFOC-20220246261(0)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
[redacted] CCYYMMDD	[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2) CA-JNJFOC-20220246261

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
JNJFOC	CA-JNJFOC-20220246261

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - JANSSEN INC

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1951[redacted] CCYYMMDD	Elderly		70 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Stroke

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	EPOETIN ALFA	
Active Substance names (B.4.k.2.2)		
epoetin alfa		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	LFS3Z00, LFS3Z00	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Cancer anemia
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Drug discontinued	Unknown	
Additional info (B.4.k.19)		
Provide the reason why sample is not available :: Discarded		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
26.0	Stroke	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective for unapproved indication	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Drug ineffective for unapproved indication	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Full blood count decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Full blood count decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Related

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 prophylaxis
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

STROKE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Stroke		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebrovascular accident		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DECREASE IN BLOOD COUNT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Full blood count decreased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Full blood count decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fall		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fall		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NOT HELPING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug ineffective for unapproved indication		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug ineffective for unapproved indication		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05301736 (0)	Page#6

Summary (B.5)

Case narrative (B.5.1)

This solicited report received from a health care professional via [redacted] BioAdvance REMICADE SIMPONI STELARA IMBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA concerned a 70 year old male (local case ID# [redacted]
The patient's height, and weight were not reported. The patient's concurrent conditions included: myelodysplastic syndrome, and anemia due to myelodysplastic syndrome. The patient had no history of known drug allergies.
The patient was treated with epoetin alfa (solution for injection, subcutaneous, batch number: LFS3Z00, expiry: 01-NOV-2022) dose, frequency were not reported from [redacted] for anemia due to myelodysplastic syndrome. The patient received the non-company suspect drug included COVID-19 vaccine (formulation, route of administration not reported) dose, frequency and therapy dates not reported for COVID-19 prophylaxis. No concomitant medications were reported. It was reported that, due to underlying conditions and second dose of COVID-19 vaccine patient's condition worsened. After 2nd dose, went to hospital a couple times but was sent home and was okay during summer but after OCT everything worsened and snowballed with falling, stroke, and decrease in blood count. The patient actually had 1 injection before he had was admitted to hospital. Hospital was given 3 doses of the injection to use for patient and told her not helping. The patient was in hospital about a month and on [redacted] the patient died due to stroke. It was unknown if an autopsy was performed.
Treatment with epoetin alfa was withdrawn with respect to stroke, action taken with epoetin alfa was not reported for decrease in blood count, fall, and not helping.
Action taken with COVID-19 vaccine was not applicable with respect to stroke and not helping, action taken with epoetin alfa was not reported for decrease in blood count, and fall.
The outcome of the decrease in blood count, fall, and not helping was not reported.
The reporter considered the causality between epoetin alfa, and stroke as not related. The reporter did not provide a causality assessment between epoetin alfa, and decrease in blood count, fall, and not helping. Company causality between epoetin alfa, and stroke was related. Company causality between epoetin alfa, and decrease in blood count, fall, and not helping was not related.
This report was serious (Death, Hospitalization Caused / Prolonged, and Other Medically Important Condition).
This case, involving the same patient is linked to 20220126446.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

V0: Cerebrovascular accident. This event is labeled per RSI and is therefore considered potentially related.

Fall blood count decreased. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: UNDERLYING DISEASE. Therefore, this event is considered not related.

Fall. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: NATURE OF EVENT. Therefore, this event is considered not related.

Drug ineffective for unapproved indication. This event is labeled by standard procedures. Therefore, the event is considered not related.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood count	decreased	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
decreased			

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myelodysplastic syndrome	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cancer anemia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Stroke

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

the patient had no history of known drug allergies

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05301736 (0)	Page#8

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
Miss.	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c): [redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Other health professional

Literature reference(s) (A.2.2):

Study name (A.2.3.1)	Project No
BioAdvance REMICADE SIMPONI STELARA IMBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
[redacted]	Other studies

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05302214 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220505 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200298752(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
2022[redacted] CCYYMMDD	20220503 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200298752

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200298752

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			37 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05302214 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Pulmonary embolus

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)
26.0	Pulmonary embolus

Drug (B.4)

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Canada Vigilance AER#:	E2B_05302214 (2)	Page#3

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)** FN7934	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12) 2022[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2022[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 255 Hours	**Last period (B.4.k.13.2)** 255 Hours	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pulmonary embolus	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pulmonary embolus	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MYA	
Active Substance names (B.4.k.2.2)		
ethinyl estradiol drospirenone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02415380 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Contraception Acne
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ISOTRETINOIN	
Active Substance names (B.4.k.2.2)		
isotretinoin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Acne
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PULMONARY EMBOLUS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary embolus		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pulmonary embolism		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
255 Hours	255 Hours	Fatal

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05302214 (2)	Page#6

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Physician).

A 37-year-old female patient (not pregnant) received BNT162b2 (COMIRNATY), on [redacted]2022 as dose 1, single (Lot number: FN7934) at the age of 37 years intramuscular, in left deltoid for covid-19 immunisation. The patient's relevant medical history included: "Obesity" (unspecified if ongoing), notes: Moderately obese; "Acne" (unspecified if ongoing); "Contraceptive" (unspecified if ongoing). Concomitant medication(s) included: MYA taken for contraception, acne; ISOTRETINOIN taken for acne.
The following information was reported: PULMONARY EMBOLISM (death, medically significant) with onset [redacted]2022 at 15:00, outcome "fatal", described as "Pulmonary embolus". The event "pulmonary embolus" required emergency room visit. The patient underwent the following laboratory tests and procedures: SARS-CoV-2 test: [redacted]2022) Negative. It was unknown if therapeutic measures were taken as a result of pulmonary embolism. The patient date of death was [redacted]2022. Reported cause of death: "Pulmonary embolus - unknown source". The autopsy revealed "pulmonary embolus -unknown source" (pulmonary embolism).

Clinical course: Post the vaccination, the patient has not been tested for COVID-19. Physician reported that prior to patients death, patient was fine. On [redacted]2022, approximately 3 pm She was preparing dinner and took her 2-year old child to the bathroom. As she was walking back to the kitchen, she collapsed, clutched her chest, and complained that she cant breathe. Her husband called emergency medical services (EMS). She was taken inside an ambulance where the first responders tried to resuscitate her for 40 minutes but patient expired. Preliminary cause of death per coroner was massive embolism without known source. Autopsy was conducted and results are pending. The report of autopsy that was done and confirmed pulmonary embolism. He was told that the final autopsy report will be completed by [redacted]022. Preliminary diagnosis per coroner - pulmonary embolus unknown source. Age 37 - health, on long term oral contraceptive since birth of last child in [redacted]019, other wise healthy but moderately obese. No prior lung diseases or health issues. At the time of diagnosis, patient was negative of COVID and never had it. No investigations done before patients death. However, physician suggested that Pfizer contact the primary HCP to reconfirm this. Physician is not sure as he was not there but he believes the patient received a type of adrenaline when the first responders were trying to revive her. She might have received oxygen as well towards the end but he knows for a fact that she did not get oxygen right away. Patient was taking Mya both as a contraceptive and acne medication for about 8-9 months (exact start and end dates unknown). She also used an isotretinoin cream (exact name, strength, start and end dates unknown) for acne. No family history of blood clots (thrombophilia) or other bleeding disorders. Other risk factors for thrombosis included moderate obesity. Physician confirmed that the patient was a non-smoker and a non-drinker.

Follow-up attempts completed. No further information is expected.

Follow-up (21Apr2022): The following information was received as response to the follow-up questionnaire from the same contactable physician (also cousin of patient's husband). Updated information: Anatomical location updated to "Deltoid left". Emergency room checkbox ticked, as per source document. Obesity added as medical history.

Follow-up attempts completed. No further information is expected.

Follow-up (03May2022): This is a follow-up report received from the same contactable physician. Updated information included: Lab data, Treatment received, Concomitant medications.

Follow-up attempts completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

As there is limited information in the case provided, the causal association between the event Pulmonary embolism and the suspect drug bnt162b2 cannot be excluded.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2022[redacted] CCYYMMDD	SARS-CoV-2 test	Negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Obesity	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)
Moderately obese

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Acne	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Contraception	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pulmonary embolus	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Physician
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05338470 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220307 CCYYMMDD
	HC Initial Received Date:	20220307 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200321451(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220223 CCYYMMDD	20220223 CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200321451

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200321451

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			48 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05338470 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2a)	Reported cause(s) (B.1.9.2b)
26.0	Cerebral venous sinus thrombosis
26.0	Hemorrhage

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EX0904	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
41085 Minutes	41085 Minutes	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral venous sinus thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Canada Vigilance AER#:	E2B_05338470 (0)	Page#3
PHARMACEUTICAL COMPANY	Global Introspection	N/A

MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Cerebral venous sinus thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CVST

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral venous sinus thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral venous sinus thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
41085 Minutes	41085 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE HEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
41085 Minutes	41085 Minutes	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP).

A 48 year-old male patient received bnt162b2 (BNT162B2), administered in arm left, administration date [redacted]2021 16:45 (Lot number: EX0904) at the age of 48 years as dose 1, single for covid-19 immunisation. COVID-19 vaccine was administered at Hospital. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: CEREBRAL VENOUS SINUS THROMBOSIS (death, hospitalization, medically significant, life threatening) with onset [redacted]2021 05:30, outcome "fatal", described as "CVST"; HAEMORRHAGE (death, hospitalization, medically significant, life threatening) with onset [redacted]021 05:30, outcome "fatal", described as "severe hemorrhage". Therapeutic measures were taken as a result of cerebral venous sinus thrombosis, haemorrhage. Patient was treated in ICU (Intensive care unit). The patient date of death was unknown. The reported cause of death was cerebral venous sinus thrombosis, haemorrhage. It was not reported if an autopsy was performed.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral venous sinus thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemorrhage	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05358681 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220420 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200387563(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220308 CCYYMMDD	20220419 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200387563

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200387563

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			8 Decade

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05358681 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022 CCYY	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05358681 (2)	Page#3

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 2022[redacted] CCYYMM	**Drug end date (B.4.k.14)** 2022[redacted] CCYYMM	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)** 12 Days	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05358681 (2)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2022		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
	12 Days	Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable Other HCP.

A male patient in his 70's received BNT162B2 (COMIRNATY), administration date [redacted]2022 (Batch/Lot number: unknown) as dose 2, single for COVID-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: COVID-19 vaccine (Dose 1, Manufacturer unknown), for COVID-19 immunisation. The following information was reported: DEATH (death) with onset 2022, outcome "fatal", described as "passed away". The cause of death was unknown. No autopsy was performed.

Clinical information: Reporter is a drug access coordinator. She is the patient's daughter. She stated that her healthy father in his 70s received a second dose of the Pfizer vaccine i[redacted] and died 12 days later. She stated that she believed the vaccine to be the cause of death. Symptoms are unknown but she did describe that her father was hospitalized before he passed and that she refused autopsy or further investigation of cause of death. Optional Information: She did go on to say that she still believed in the greater good of the vaccine.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (09Mar2022): This is a spontaneous follow-up report received from a contactable other HCP (Pfizer Colleague).
Updated information: Historical vaccine and Reporter contact information.

Follow-up (19Apr2022): This follow-up is being submitted to notify that the lot/batch number for all doses are not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

As there is limited information in the case provided, the causal association between the event Death and the suspect BNT162B2 cannot be excluded.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Unknown cause of death		
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**	

Comments (B.1.7.1g)

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)
COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	**Indication (B.1.8f.2)** COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220314 CCYYMMDD
	HC Initial Received Date:	20220314 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200370729(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220304 CCYYMMDD	20220304 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200370729

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200370729

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CALLER REPORTS THAT A DOCTOR IS NOW DEAD FROM THE VACCINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) from medical information team.

A patient (no qualifiers provided) received bnt162b2 (COMIRNATY) (Batch/Lot number: unknown) as dose number unknown, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEATH (death), outcome "fatal", described as "Caller reports that a doctor is now dead from the vaccine". The patient date of death was unknown. The reported cause of death was "is now dead". It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05369941 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220818 CCYYMMDD	
	HC Initial Received Date: 2022 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A112677()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220314 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220816 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2022A112677

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) HEALTH CANADA MC Canada Adverse Reaction Report Number AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** 000974901 [redacted] 000974901 CA-AstraZeneca-2022A112677

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Confusional state
26.0	Decreased appetite
26.0	Lethargy
26.0	Mobility decreased

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CONFUSIONAL STATE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Confusional state		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Confusional state		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DECREASED APPETITE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Decreased appetite		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Decreased appetite		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LETHARGY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lethargy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Lethargy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MOBILITY DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Mobility decreased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Mobility decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a health professional via the regulatory authority in Canada concerning a female patient (age not provided) of unknown ethnic origin.

The patient's past and current medical history included acute myeloid leukemia (dates not reported), stroke (dates not reported) and chronic pain (dates not reported) and No concomitant products were reported.

On an unknown date, the patient received dose unknown of Covid-19 Vaccine (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route for an unknown indication.

On an unknown date, the patient experienced confusional state (preferred term: Confusional state), decreased appetite (preferred term: Decreased appetite), lethargy (preferred term: Lethargy), mobility decreased (preferred term: Mobility decreased). The reporter stated that the hospital stated that the acute myeloid leukemia was recent and aggressive.

It was unknown if any action was taken with Covid-19 Vaccine.

During 2021, the patient died from the event of confusional state, decreased appetite, lethargy and mobility decreased.

It was not known whether an autopsy was performed. The cause of death was confusional state, decreased appetite, lethargy and mobility decreased.

The reporter assessed the events of confusional state, decreased appetite, lethargy and mobility decreased to be serious due to the seriousness criterion of death.

On an unknown date, the patient was tested for several blood test with results which does not showed up low counts of WBCs.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Summary of follow up information received by AstraZeneca/MedImmune on 16-Aug-2022 from the health professional via Spontaneous Source: Year of death were added. Concomitant diseases added. Relevent history added. Lab test added. Narrative amended.CAUSE OF DEATH: CONFUSIONAL STATE CAUSE OF DEATH: DECREASED APPETITE CAUSE OF DEATH: LETHARGY CAUSE OF DEATH: MOBILITY DECREASED CONFUSIONAL STATE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DECREASED APPETITE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes LETHARGY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MOBILITY DECREASED - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes Lab Test #1 : 10061726 The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal events of Confusional state and Mobility decreased are not listed in the company core data sheet of AZD1222. Decreased appetite and Lethargy are listed adverse events for AZD1222. However, since the events are reported with the seriousness criteria of death the events are considered unlisted. Cause of death was further specified as Confusional state, Mobility decreased, Decreased appetite and Lethargy. Reported history of acute myeloid leukemia could be considered as contributory factor for the event of Lethargy and Decreased appetite. Reported past and current medical history of stroke could be considered as risk factor for the event of Confusional state and Mobility decreased. Relevant past and current medical history of chronic pain could be considered as risk factor for the event of Lethargy and Mobility decreased. Due to limited information on exact circumstances leading to the events, exact date of vaccination, event onset dates, the clinical course, medical history, concurrrent conditions, concomitant medications, autopsy details, risk factors leading to the events, detailed etiological and diagnostic workup, the evaluation did not find evidence to suggest a causal relationship between events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood test	Low WBC count never showed up in lab report	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Acute myeloid leukemia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Unknown	

Comments (B.1.7.1g)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Stroke	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chronic pain	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Confusional state	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Decreased appetite	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Lethargy	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Mobility decreased	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	HEALTH CANADA

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05395819 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200463295(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220315 CCYYMMDD	20220414 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-PFIZER INC-202200463295

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200463295

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05395821, (2) E2B_05395821

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral thrombosis
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

ATIA - 19(1)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted].

A patient (no qualifiers provided) received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: MYOCARDIAL INFARCTION (death), outcome "fatal", described as "heart attacks"; CEREBRAL THROMBOSIS (death), outcome "fatal", described as "brain clots". The patient date of death was unknown. Reported cause of death: "heart attacks", "brain clots". It was unknown if an autopsy was performed.

Clinical courses: the reporter can not confirm if the patient took Pfizer or Moderna.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Apr2022): This is a spontaneous follow-up report from the same contactable consumer.
Updated information included: new events (heart attacks, brain clots).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05395819 (1)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05395821 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200463293(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220315 CCYYMMDD	20220414 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200463293

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200463293

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05395819, (2) E2B_05395852, (2) E2B_05395857, (2) E2B_05395856, (2) E2B_05395860, (2) E2B_05395856, (2) E2B_05395860, (2) E2B_05395819, (2) E2B_05395852, (2) E2B_05395857

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05395821 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral thrombosis
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral thrombosis	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral thrombosis	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05395821 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted]

A patient (no qualifiers provided) received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: MYOCARDIAL INFARCTION (death), outcome "fatal", described as "heart attacks"; CEREBRAL THROMBOSIS (death), outcome "fatal", described as "brain clots". The patient date of death was unknown. Reported cause of death: "heart attacks", "brain clots". It was unknown if an autopsy was performed.

Clinical courses: the reporter can not confirm if the patient took Pfizer or Moderna.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Apr2022): This is a spontaneous follow-up report from the same contactable consumer.
Updated information included: new events (heart attacks, brain clots).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05395849 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200417791(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220315 CCYYMMDD	20220414 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200417791

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200417791

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Organ failure
26.0	Sepsis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Organ failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05395849 (1)	Page#3

MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Organ failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sepsis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sepsis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ALL ORGANS SHUT DOWN, SEPSIS SET IN AND SHE DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Organ failure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Organ failure		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ALL ORGANS SHUT DOWN, SEPSIS SET IN AND SHE DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Sepsis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Sepsis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted]

A female patient (unknown if pregnant) received BNT162b2 (COMIRNATY), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: ORGAN FAILURE (death), SEPSIS (death), outcome "fatal" and all described as "all organs shut down, sepsis set in and she died". The patient date of death was unknown. Reported cause of death: "all organs shut down, sepsis set in". It was unknown if an autopsy was performed.

Clinical courses: The death occurred within a month of receiving the vaccine.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Apr2022): This is a spontaneous follow-up report from the same contactable consumer.
Updated information included: Patient's gender, new events (organ failure and sepsis).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Organ failure	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Sepsis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05395852 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200463296(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220315 CCYYMMDD	20220414 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200463296

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200463296

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05395821, (2) E2B_05395821

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral thrombosis
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted]

A patient (no qualifiers provided) received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: MYOCARDIAL INFARCTION (death), outcome "fatal", described as "heart attacks"; CEREBRAL THROMBOSIS (death), outcome "fatal", described as "brain clots". The patient date of death was unknown. Reported cause of death: "heart attacks", "brain clots". It was unknown if an autopsy was performed.

Clinical courses: the reporter can not confirm if the patient took Pfizer or Moderna.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Apr2022): This is a spontaneous follow-up report from the same contactable consumer.
Updated information included: new events (heart attacks, brain clots).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI*

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
97 ans ____ mois	☐ Homme ☑ Femme	____ cm ____ pi ____ po	57.3 kg ____ lbs ____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

AVC coronaradiata frontal g 14/06/2021
HTO, diabète type 2, hypoTH,
TNCM mixtes modérés.

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]		

4. Adresse	5. Courriel
[redacted]	

6. Langue préférée
☑ français
☐ anglais

7. Organisation (le cas échéant)
[redacted]

8. Choisir ce qui vous décrit le mieux
☐ Consommateur ou autre non-professionnel de la santé ☑ Médecin ☐ Pharmacien
☐ Autre professionnel de la santé (spécifier) : _____

9. Cela a-t-il été déclaré au fabricant?
☐ Oui ☑ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire
☑ Décès (fournir la date) [redacted] 2021.
☐ Met la vie en danger
☐ Hospitalisation
☐ Prolongation d'une hospitalisation
☐ Incapacité
☐ Malformation congénitale
☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*
☐ Oui ☑ Non ☐ Inconnu
☐ En cours de rétablissement (expliquer) : _____

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)
[redacted] 2021	décès [redacted] 2021

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

Confusion dès le lendemain du vaccin. HTA labile et altération de l'état de conscience dès le [redacted] 2021 <-> Altération de l'état de conscience a persisté jusqu'au décès.

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
PBCOVID-19		Pfizer.

4. N° du lot	5. N° du DIN / N° du NPN
FA9099	

6. Pays d'achat
☑ Canada
☐ États-Unis
☐ Autre (spécifier) : _____

7. Où le produit a-t-il été acheté/obtenu?
☐ Pharmacie
☐ Épicerie
☐ Internet
☑ Autre (spécifier) : Centre de foires d'expocité.

8. Date du début du traitement (aaaa-mm-jj)*
2021-[redacted] 2e dose

9. Date de la fin du traitement (aaaa-mm-jj)

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
0.3 mL.	—	IM.

13. Pourquoi le produit a-t-il été pris/prescrit?*
2e dose vaccin.

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☐ Oui ☐ Non	☐ Oui ☑ Non ☐ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ☐ Non ☑ Ne s'applique pas	☐ Oui ☐ Non ☑ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire
☐ Certain
☐ Probablement/vraisemblablement
☐ Possiblement
☑ Pas disponible / incapable de vérifier
☐ Improbable
☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)
neutraline, novarc, lorenox.

20. Tests/données de laboratoire pertinents
FSC, ions, urée, créat @ [redacted] 2021
Famille a demandé des soins palliatifs et TDM tête n'a pu être effectué.

* Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada

Pub. : 150143 | Date : avril 2020

Santé Canada Health Canada

Canada

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Canada Vigilance AER#:	E2B_05395856 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200463298(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220315 CCYYMMDD	20220414 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200463298

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200463298

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05395821, (2) E2B_05395821

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral thrombosis
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral thrombosis	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral thrombosis	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05395856 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted]

A patient (no qualifiers provided) received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: MYOCARDIAL INFARCTION (death), outcome "fatal", described as "heart attacks"; CEREBRAL THROMBOSIS (death), outcome "fatal", described as "brain clots". The patient date of death was unknown. Reported cause of death: "heart attacks", "brain clots". It was unknown if an autopsy was performed.

Clinical courses: the reporter can not confirm if the patient took Pfizer or Moderna.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Apr2022): This is a spontaneous follow-up report from the same contactable consumer.
Updated information included: new events (heart attacks, brain clots).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05395856 (1)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05395857 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200463297(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220315 CCYYMMDD	20220414 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200463297

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200463297

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05395821, (2) E2B_05395821

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05395857 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral thrombosis
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Canada Vigilance AER#:	E2B_05395857 (1)	Page#3

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)
Suspect	COVID-19 VACCINE

Active Substance names (B.4.k.2.2)

Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)
Canada	

Holder and authorization/application no. of drug (B.4.k.4)
Country of authorization/application: Canada

Structured dosage info (B.4.k.5)

Dosage text (B.4.k.6)
DOSE NUMBER UNKNOWN, SINGLE

Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	

Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunisation

Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	

Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)

Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)
Not Applicable	

Additional info (B.4.k.19)

Drug Recurrence (B.4.k.17)

MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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ATIA - 19(1)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted]

A patient (no qualifiers provided) received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: MYOCARDIAL INFARCTION (death), outcome "fatal", described as "heart attacks"; CEREBRAL THROMBOSIS (death), outcome "fatal", described as "brain clots". The patient date of death was unknown. Reported cause of death: "heart attacks", "brain clots". It was unknown if an autopsy was performed.

Clinical courses: the reporter can not confirm if the patient took Pfizer or Moderna.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Apr2022): This is a spontaneous follow-up report from the same contactable consumer.
Updated information included: new events (heart attacks, brain clots).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05395857 (1)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05395860 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200463299(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220315 CCYYMMDD	20220414 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200463299

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200463299

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05395821, (2) E2B_05395821

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05395860 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral thrombosis
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05395860 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted]

A patient (no qualifiers provided) received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: MYOCARDIAL INFARCTION (death), outcome "fatal", described as "heart attacks"; CEREBRAL THROMBOSIS (death), outcome "fatal", described as "brain clots". The patient date of death was unknown. Reported cause of death: "heart attacks", "brain clots". It was unknown if an autopsy was performed.

Clinical courses: the reporter can not confirm if the patient took Pfizer or Moderna.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Apr2022): This is a spontaneous follow-up report from the same contactable consumer.
Updated information included: new events (heart attacks, brain clots).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05395860 (1)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05436539 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220810 CCYYMMDD	
	HC Initial Received Date: 2022 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A139288()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220404 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220808 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2022A139288

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MAH AER NUMBER MC-Canada AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_04949516 202101654766 [redacted] CA-AstraZeneca-2022A139288

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 56 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05436539 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Asthma
26.0	Product dose omission issue

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100.0mg UNKNOWN		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Asthma
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ASTHMA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Asthma		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Asthma		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRODUCT DOSE OMISSION ISSUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Product dose omission issue		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Product dose omission issue		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a Health Professional via the regulatory authority in Canada (canadian health authority) concerning a 56-year-old female patient of Unknown ethnic origin.

No medical history and concomitant products were reported.

On an unknown date, the patient received Covid-19 Vaccine Astrazeneca (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number Unknown), via intramuscular route, for covid-19 immunisation.

On an unknown date, the patient started treatment with Comirnaty Vial Contains 6 Doses Of 0.3 ml after Dilution (tozinameran) for covid-19 immunisation and Mepolizumab (mepolizumab) 100.0 Milligram, subcutaneous, for asthma.

On an unknown date, the patient experienced asthma (preferred term: Asthma) and product dose omission issue (preferred term: Product dose omission issue).

It was not applicable if any action was taken with Covid-19 Vaccine Astrazeneca, Comirnaty Vial Contains 6 Doses Of 0.3 ml after Dilution and it was unknown if any action was taken with Mepolizumab.

The patient died from the event of asthma and product dose omission issue on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was asthma and product dose omission issue

The reporter assessed the events of asthma and product dose omission issue to be serious due to seriousness criteria of death.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Summary of follow up information received by Astrazeneca/Medimmune on 08-Aug-2022 from Health Professional via spontaneous source: Reporter updated to HCP, Reference numbers added, Action taken updated to not applicable. Narrative amended.CAUSE OF DEATH: ASTHMA CAUSE OF DEATH: PRODUCT DOSE OMISSION ISSUE ASTHMA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PRODUCT DOSE OMISSION ISSUE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Asthma and Product dose omission issue are not listed in the company core data sheet of AZD1222. Notable, that concomitant medication included Mepolizumab (mepolizumab) 100.0 Milligram, subcutaneous, for asthma. Due to limited information on risk factors, date of the vaccination, circumstances surrounding the events, relevant medical and family history, detailed etiological and diagnostic work-up (complete blood analysis including inflammatory markers, general physical examination, radiology imaging studies), treatment details and in the absence of autopsy report, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Asthma	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Product dose omission issue	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Source Document: Source Document: 2022-04-04 exportPDF COVID-19 VACCINE

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) UNKNOWN	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) CANADIAN HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) UNKNOWN	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) UNKNOWN
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05453849 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220411 CCYYMMDD	
	HC Initial Received Date: 20220411 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200538891(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220407 CCYYMMDD	20220407 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-PFIZER INC-202200538891

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_05011774 20211214858 CA-PFIZER INC-202200538891

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			69 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cholelithiasis
26.0	Crohn's disease
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cholelithiasis	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Crohn's disease	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
520 Milligram		
Dosage text (B.4.k.6)		
520 mg, 1 every 8 Weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Crohn's disease
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHOLELITHIASIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cholelithiasis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cholelithiasis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CROHN'S DISEASE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Crohn's disease		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Crohn's disease		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

NON-INTERVENTIONAL POST-MARKETING STUDY - PROTOCOL TITLE NOT AVAILABLE

This is a non-interventional study report received from a contactable reporter(s) (Pharmacist) from Regulatory Authority. Regulatory number: E2B_05011774 (Health Canada).

A 69-year-old female patient received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) intramuscular for covid-19 immunisation; ustekinumab (STELARA), (Batch/Lot number: unknown) at 520 mg (520 mg, 1 every 8 weeks), intravenous for crohn's disease. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: CHOLELITHIASIS (death, medically significant), outcome "fatal"; CROHN'S DISEASE (death, medically significant), outcome "fatal"; DEATH (death, medically significant), outcome "fatal". The action taken for ustekinumab was unknown. The date and cause of death for the patient were unknown.

The reporter's assessment of the causal relationship of "cholelithiasis", "crohn's disease" and "death" with the suspect product(s) COVID-19 Vaccine - Manufacturer Unknown was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on known drug safety profile, there is reasonable possibility of causal association between the events CHOLELITHIASIS, CROHN'S DISEASE, and DEATH and BNT162B2.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cholelithiasis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Crohn's disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Pharmacist	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3) Other studies	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05473491 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220504 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200582438(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Published		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220414 CCYYMMDD	20220430 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

PU#1 (PRD/SRD: 30APR2022) Full publication,Initial (PRD/SRD 14Apr2022) Full publication

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) CA-PFIZER INC-202200582438

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200582438

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			27 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Antibody-mediated rejection
26.0	Clostridium difficile infection

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Antibody-mediated rejection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Antibody-mediated rejection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clostridium difficile infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clostridium difficile infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Organizing pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Organizing pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) METHYLPREDNISOLONE	
Active Substance names (B.4.k.2.2) methylprednisolone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Rejection acute hepatic
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CLOSTRIDIUM DIFFICILE INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clostridium difficile infection		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Clostridium difficile infection		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

[redacted]

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Antibody-mediated rejection		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Transplant rejection		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ORGANIZING PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Organizing pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Organising pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a literature report for the following literature source(s): [redacted]

A 27-year-old male patient received BNT162b2 (BNT162B2), as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history included: "bilateral lung transplant recipient" (unspecified if ongoing); "cystic fibrosis" (unspecified if ongoing); "Antibody-Mediated Rejection" (unspecified if ongoing); "grade 2 rejection" (unspecified if ongoing). Concomitant medication(s) included: METHYLPREDNISOLONE taken for liver transplant rejection. Vaccination history included: Bnt162b2 (Dose 1|, for covid-19 immunization.The following information was reported: CLOSTRIDIUM DIFFICILE INFECTION (death, hospitalization, medically significant), outcome "fatal"; TRANSPLANT REJECTION (death, hospitalization, medically significant), outcome "fatal", described as [redacted] ORGANISING PNEUMONIA (death, hospitalization, medically significant), outcome "fatal", described as "organizing pneumonia". The patient underwent the following laboratory tests and procedures: Antibody test: decreased but remained elevated; Bronchoscopy: Negative, notes: infectious etiology; Computerised tomogram: findings consistent with organizing pneumonia, notes: versus opportunistic infection; HLA marker study: [redacted] notes: [redacted] Therapeutic measures were taken as a result of clostridium difficile infection, transplant rejection, organising pneumonia. The patient date of death was unknown. Reported cause of death: [redacted] "Clostridium difficile infection". It was not reported if an autopsy was performed [redacted] This case of probable AMR post mRNA vaccination in a lung transplant recipient raises clinical suspicion for a serious adverse event and contributes to safety data for this select population.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (30Apr2022):This is a literature report for the following literature source(s): [redacted] This is a follow-up report based on the receipt of the publication; the case has been updated to include additional information identified in the publication.Updated information included narrative updated with follow up statement.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the information provide and plausible temporal association, the causality between BNT162B2 and events cannot be completely excluded.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Antibody test	decreased but remained elevated	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Bronchoscopy	Negative	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	CT scan	findings consistent with organizing pneumonia	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Human leukocyte antigen test	[redacted]	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes

Results of tests and procedures (B.3.2)

HLA marker study():and[redacted]
Bronchoscopy():infectious etiology
Computerised tomogram():versus opportunistic infection

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Lung transplant	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cystic fibrosis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Antibody-mediated rejection	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Rejection chronic hepatic	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clostridium difficile infection	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Antibody-mediated rejection	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

BNT162B2

Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	**DOB of Parent** (B.1.10.2.1)	**Age** (B.1.10.2.2)	**LMP date** (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	**Medical history** (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05473491 (1)	Page#9

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	Department of Medicine

Reporter street (A.2.1.2c)
[redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)
[redacted]

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05474451 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220419 CCYYMMDD	
	HC Initial Received Date: 20220419 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200564731(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-PFIZER INC-202200564731

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200564731

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05474451 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 4 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
23 Hours	23 Hours	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05474451 (0)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MY AUNT TOOK YOUR 4TH VACCINE SHOT YESTERDAY / SHE DIED LAST NIGHT AT 11PM

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
23 Hours	23 Hours	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP).

A female patient received BNT162b2 (COMIRNATY), on [redacted]2022 as dose 4 (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE 1; MANUFACTURER UNKNOWN), for COVID-19 immunisation; Covid-19 vaccine (DOSE 2; MANUFACTURER UNKNOWN), for COVID-19 immunisation; Covid-19 vaccine (DOSE 3; MANUFACTURER UNKNOWN), for COVID-19 immunisation.
The following information was reported: DEATH (death) with onset [redacted]2022 at 23:00, outcome "fatal", described as "My aunt took your 4th vaccine shot yesterday / She died last night at 11pm". The patient date of death was [redacted]2022. The reported cause of death was unknown.
No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_05474451 (0)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
COVID-19 VACCINE		
Start date (B.1.8c)		**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)		**Indication** (B.1.8f.2)
26.0 26.0 26.0		COVID-19 immunisation COVID-19 immunisation COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)		**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)		Medical history (B.1.10.7.1a.2)
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3)		**Qualification** (A.2.1.4)
	Canada		Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05482328 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220810 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A154136()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220418 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220808 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2022A154136

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADA HEALTH AUTHORITY MC Canada MAH AER Number AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_05011774 [redacted] 20211214858 CA-AstraZeneca-2022A154136

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 69 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	KLS0H12 KLS0H12	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
520 Milligram, 1 every 8 (weeks)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Crohns disease aggravated
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021 CCYY		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FLARE UP OF CROHNS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Crohn's disease aggravated		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Crohn's disease		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GALLSTONES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Gallstones		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cholelithiasis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a pharmacist via the regulatory authority in Canada (CANADA HEALTH AUTHORITY), concerning a 69 year old female patient of unknown ethnic origin.

The patient's past and current medical history included crohn's disease (ongoing) and unknown cause of death (dates not reported). No concomitant products were reported.

On an unknown date, the patient received unknown dose of Covid-19 Vaccine (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number Unknown), via intramuscular route, for covid-19 prophylaxis. During 2021, the patient started treatment with Stelara (ustekinumab) (batch number(s) KLS0H12 KLS0H12) (expiration date 30-Nov-2025), 520 Milligram, 1 every 8 (weeks), intravenous (not otherwise specified), for crohn's disease.

During 2021, the patient experienced flare up of crohns (preferred term: Crohn's disease) with covid vaccine, gallstones (preferred term: Cholelithiasis) and the patient passed away; died (preferred term: Death). On an unknown date, the patient had gallstones and was going for ultrasound and blood work.

Action taken with Covid-19 Vaccine and Stelara was not applicable.

The outcome of the events of flare up of crohns and gallstones was unknown.

t was unknown if autopsy was performed. The cause of death was unknown.

The reporter assessed the event of passed away to be serious due to seriousness criterion of death. The reporter assessed the events flare up of crohns, gallstones and passed away to be serious due to seriousness criterion of important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Summary of follow up information received by AstraZeneca/MedImmune on 18-Apr-2022 from Pharmacist via spontaneous source: Primary reporter changed from consumer to pharmacist, case medically confirmed ticked. Report corrected on 21-Apr-2022: New reference reporter added with the last name MAH AER Number. Narrative amended.

Summary of follow-up information received by AstraZeneca/MedImmune on 08-Aug-2022 from a pharmacist via spontaneous: Death tab updated; Date of death and cause of death (Unknown cause of death) added. Action taken for suspect products updated from Unknown to Not applicable. Outcome of events flare up of crohns and Gallstones updated from Fatal to Unknown. Details of suspect Stelara updated. Start date for all the events added. Coding and Event verbatims updated; verbatim Death updated to Passed away, Crohn's disease updated to flare up of crohns (LLT changed from Disease Crohns to Crohn's disease aggravated, Cholelithiasis to Gallstones (LLT changed from Cholelithiasis to Gallstones). New reference reporter added. Relevant history added. Date of birth added. Narrative amended.CAUSE OF DEATH: PASSED AWAY CAUSE OF DEATH: UNKNOWN CAUSE OF DEATH PASSED AWAY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes FLARE UP OF CROHNS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes GALLSTONES - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes Lab Test #1 : 10045434 Lab Test #2 : 10061726 The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case concerns a 69-year-old female vaccinee with reported Death and fatal events of Crohn's disease and Cholelithiasis in association with AZD1222. Underlying history of Crohn?s disease could be considered as confounding factor to the event of Crohn?s disease. Age of vaccinee and female gender could be considered as possible risk factors for Cholelithiasis. The cause of death was reported as death, Crohn?s disease, cholelithiasis and death. Due to limited information on baseline health condition before vaccination, relevant medical history, relevant family history, concurrent diseases, concomitant medications, date of vaccination, start date of using ustekinumab, onset date/clinical course of Crohn's disease and Cholelithiasis, date of death, details of the events, circumstances surrounding the events, further risk factors (smoking, past and recent infections, genetic predisposition), and detailed diagnostic and etiologic workup, autopsy report with confirmed diagnosis, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood test	Unknown	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Ultrasound scan	Unknown	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Crohn's disease	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) PRIVACY	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) CANADA HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) UNKNOWN	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) UNKNOWN
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Pharmacist	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

ATIA - 19(1)

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Canada Vigilance AER#:	E2B_05499967 (5)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20230127 CCYYMMDD	
	HC Initial Received Date: 2022 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2022034800(6)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2022[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20230123 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-GLAXOSMITHKLINE-CA2022034800

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) GSK GSK 01052547635	**Duplicate Case identifiers (A.1.11.2)** CA-GSK-E2B_05932303 CA-GSK-202201166442 CA-GLAXOSMITHKLINE-CA2022034800

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (1) E2B_05932303

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - GLAXOSMITHKLINE

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 93 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

ATIA - 19(1)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	BL2S	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg, Z , every 4 weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Eosinophilic asthma Eosinophilic asthma
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		259 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
ExpDT=30-JUN-2023		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sputum discolored	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sputum discolored	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sputum discolored	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sputum discolored	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0 26.0 26.0 26.0	**Indication (B.4.k.11b)** COVID-19 immunization Product used for unknown indication Product used for unknown indication Product used for unknown indication
Start date of drug (B.4.k.12) 2022[redacted] CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ADVAIR	
Active Substance names (B.4.k.2.2) salmeterol xinafoate fluticasone propionate		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 2 Dosage forms,2 every 1 (Days)		
Dosage text (B.4.k.6) 2 puff(s), bid, 25/250 2 every 1 day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Drug use for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VENTOLIN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2 Dosage forms		
Dosage text (B.4.k.6)		
2 puff(s), Z 100 mcg as needed		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	INSPIOLTO	
Active Substance names (B.4.k.2.2)		
OLODATEROL HYDROCHLORIDE TIOTROPIUM BROMIDE		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	SPIRIVA	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2 Dosage forms,1 every 1 (Days)		
Dosage text (B.4.k.6)		
2 puff(s), qd, 2.5 mcg 1 every 1 day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PREGABALIN	
Active Substance names (B.4.k.2.2)		
pregabalin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
25 Milligram		
Dosage text (B.4.k.6)		
25 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
2022[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	OLODATEROL HYDROCHLORIDE + TIOTROPIUM BROMIDE MONOHYDRATE	
Active Substance names (B.4.k.2.2)		
OLODATEROL HYDROCHLORIDE TIOTROPIUM BROMIDE MONOHYDRATE		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THAT PATIENT IS DECEASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

LUNG INFECTION [redacted] PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pneumonia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERMITTENT COUGH/INTERMITTENT DRY COUGH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cough
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Cough

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DARK GREEN MUCUS SINCE PAST WEEK/WHITE SECRETIONS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sputum discolored
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Sputum discoloured

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRODUCTIVE COUGH WITH WHITE SECRETIONS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Productive cough
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Productive cough

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CURRENT INJECTION [redacted]2022) OUTSIDE THE 7-DAY TREATMENT WINDOW

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Drug dose administration interval too long
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Inappropriate schedule of product administration

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

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	20220430		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
232 Days		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This case was reported by a consumer via regulatory authority and described the occurrence of unknown cause of death in a 93-year-old male patient who received mepolizumab solution for injection in pre-filled pen (batch number BL2S, expiry date 30th June 2023) for eosinophilic asthma.

Co-suspect products included mepolizumab autoinjector device administration system (batch number BL2S, expiry date 30th June 2023) for eosinophilic asthma, mepolizumab solution for injection in pre-filled pen (batch number H36E, expiry date 30th September 2023) for eosinophilic asthma, mepolizumab autoinjector device administration system (batch number H36E, expiry date 30th September 2023) for eosinophilic asthma and tozinameran (Comirnaty) solution for injection for covid-19 immunization.

Additional subject notes included Patient was Afebrile. Patient history was unknown.. Concomitant products included fluticasone propionate + salmeterol xinafoate (Advair), salbutamol (Ventolin), olodaterol hydrochloride + tiotropium bromide (Inspiolto), tiotropium bromide (Spiriva), pregabalin and olodaterol hydrochloride + tiotropium bromide monohydrate.

On [redacted] 2021, the patient started mepolizumab (subcutaneous) 100 mg (see dose text), mepolizumab autoinjector device, mepolizumab (subcutaneous) 100 mg (see dose text) and mepolizumab autoinjector device. On an unknown date, the patient started Comirnaty at an unknown dose and frequency. On an unknown date, the dose was changed to an unknown dose and frequency. On an unknown date, the dose was changed to an unknown dose and frequency. O[redacted] 2022, the dose was changed to an unknown dose and frequency. On [redacted] 2022, 232 days after starting mepolizumab, mepolizumab autoinjector device, mepolizumab and mepolizumab autoinjector device, the patient experienced drug dose administration interval too long (serious criteria hospitalization and other: Serious per Reporter). On an unknown date, the patient experienced unknown cause of death (serious criteria death and GSK medically significant), pneumonia (serious criteria hospitalization, GSK medically significant and other: Serious per Reporter), cough (serious criteria hospitalization and other: Serious per Reporter), sputum discolored (serious criteria hospitalization and other: Serious per Reporter) and productive cough (serious criteria hospitalization and other: Serious per Reporter). The subject was treated with prednisone and antibiotics nos (Antibiotic (Active Ingredient Unknown)). On an unknown date, the outcome of the unknown cause of death was fatal and the outcome of the pneumonia was not recovered/not resolved and the outcome of the drug dose administration interval too long, cough, sputum discolored and productive cough were unknown. The reported cause of death was unknown cause of death.

It was unknown if the reporter considered the unknown cause of death, pneumonia, cough, sputum discolored, productive cough and drug dose administration interval too long to be related to mepolizumab, mepolizumab autoinjector device, mepolizumab and mepolizumab autoinjector device. This report is made by GSK without prejudice and does not imply any admission or liability for the incident or its consequences.

Linked case(s) involving the same patient:CA2021AMR209964, CA2022016112

GSK Receipt Date:[redacted] 2022
Reporter's Comments: This report was submitted via the online direct entry reporting system. The patient was also the reporter. Reporter type was consumer. Post infusion report mentioned that the patient with intermittent cough but stable. Wife present. Patient said he had dark green mucus since past week and was afebrile. Patient was advised via phone by his physician yesterday[redacted] 2022) to start his action plan. Patient said he would start his Prednisone and antibiotic this afternoon[redacted] 2022). Injection well tolerated. No issues. Patient stable at writer's departure. No further information provided. Patient history was unknown. Reporter and Health Care Provider (HCP) did not consent to contact.

Follow-up information received on[redacted] 2022. This follow-up was considered significant.
It was reported that on an unknown date patient experienced productive cough. On an unknown date, outcome of the event productive cough. The causality of the event productive cough was unknown. Reporter's Comments: Post infusion report: Patient stable, wife present. Intermittent dry cough noted. Patient had productive cough with white secretions yesterday evening per wife. Respiratory therapist present. Nasal O2 was adjusted from 8LPM to 7.5LPM as O2 sat reading was 96%. Injection tolerated well. No issues. Patient stable at depart. No further information provided. Summary of changes: Added additional event, batch number of suspect drug.

Follow-up information received on[redacted] 2022. This follow-up was considered significant
Reporter's Comments: Patient's wife reported patient was currently hospitalized since last week. Wife did not provide reason of hospitalization.
Summary of Changes: Event tab got updated.

Follow-up information received on[redacted] 2022. This follow-up was considered significant.
Reporter's Comments:[redacted] 2022 Post infusion report: Patient hospitalized for lung infection[redacted]
Patient on prednisone 5mg[redacted] 2022. New medicine[redacted] 2022 pregabalin 25mg. Patient had 4th dose Covid-19 pfizer vax[redacted] 2022. Patient had appointment with doctor[redacted] 2022. Injection well tolerated. No issues. Patient stable at departure. Patient missed scheduled dose of injection on[redacted] 2022. Patient's current injection[redacted] 2022) outside the 7-day treatment window. Last dose of drug was administered on[redacted] 2022. It was unknown if the reporter considered Lung infection to be related to covid 19 vaccine. No further information provided.
Summary of Changes: Suspect, concomitant, event, narrative.

Follow-up information received on[redacted] 2022. This follow-up was considered significant.
Reporter's Comments: This case was received via Nucala Patient Support Program (Vista). Mepolizumab dose was given every 4 weeks.Patient's wife reported patient currently hospitalized due to lung infection since past 3 weeks. It was unknown if the reporter considered the lung infection, cough, sputum discolored and productive cough to be related to Comirnaty. No further information provided.
Summary of Changes: New Batch number added for Mepolizumab

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Follow up information received on [redacted]2022. This follow-up was considered significant.
Reporter's Comments: Patient was moved to palliative approach, nucala was to be stopped. No further information provided.
Summary of Changes: Product details updated. Narrative information updated.
Additional supportive information: Mepolizumab drug used by patient was Nucala.

Follow-up information received on [redacted]2022. This follow-up was considered significant.
Reporter's Comments: Case was received by pharmacist via Nucala Patient Support Program (Vista). It was reported that patient was deceased. No further information provided. It was unknown if the reporter considered the unknown cause of death, lung infection, cough, sputum discolored and productive cough to be related to Comirnaty.
Summary of Changes: Product and event details updated.

Follow up information was received on 23 Jan 2023
Reporters comment-This case was received from Health Canada. It was unknown if autopsy was performed. It was unknown if the reporter considered the drug dose administration interval too long to be related to Comirnaty.
Summary of changes-events seriousness added, formulations updated, concomitant added, causality updated

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Death, pneumonia, cough, sputum discolored, productive cough and inappropriate schedule of product administration are unlisted events which are considered unrelated to GSK drug Mepolizumab and Mepolizumab autoinjector device.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Oxygen saturation	96	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
%			Yes

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Patient was Afebrile. Patient history was unknown.

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

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Canada Vigilance AER#:	E2B_05499967 (5)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05499967 (5)	Page#16

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Mepolizumab Patient Support Program	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
Mepolizumab_PSP	Other studies

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Mepolizumab Patient Support Program	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
Mepolizumab_PSP	Other studies

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Mepolizumab Patient Support Program	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
Mepolizumab_PSP	Other studies

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Canada Vigilance AER#:	E2B_05499967 (5)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05505054 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220426 CCYYMMDD
	HC Initial Received Date:	20220426 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200620966(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220422 CCYYMMDD	20220422 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200620966

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200620966

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			88 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Leg pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Leg pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LEG PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Leg pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pain in extremity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP).

An 88-year-old male patient received BNT162b2 (COMIRNATY), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PNEUMONIA (death, medically significant), outcome "fatal"; THROMBOSIS (medically significant), outcome "unknown", described as "blood clot"; PAIN IN EXTREMITY (non-serious), outcome "unknown", described as "Leg pain". The event "blood clot" required emergency room visit. Therapeutic measures were taken as a result of thrombosis. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

Clinical course: Patient had leg pain. Got the vaccine, went to the hospital and he had a blood clot and he got started on the blood clot medication. Then the doctors said that it was pneumonia, they took him off the medication and he died within 6 hours.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

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Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05505054 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Canada Vigilance AER#:	E2B_05511992 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230227 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200192494(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220202 CCYYMMDD	20230224 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200192494

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200192494

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			17 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Enlargement heart

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 33 Days	**Last period (B.4.k.13.2)** 33 Days	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Dark circles under eyes	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Dark circles under eyes	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Enlargement heart	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Enlargement heart	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Rash generalised	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Rash generalised	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shoulder soreness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shoulder soreness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HIS MOTHER FOUND HIM DEAD ON THE FLOOR NEXT TO HIS BED/ AN AUTOPSY SHOWED THAT HIS SON'S HEART WAS "SLIGHTLY ENLARGED", BUT HE COULD NOT DETERMINE WITH CERTAINTY THE CAUSE OF DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Enlargement heart		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cardiomegaly		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
33 Days	33 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE WENT TO THE HOSPITAL ON [redacted] WITH A BAD REACTION. HE HAD A RASH ALL OVER HIS NECK AND FACE AND BROWN CIRCLES AROUND HIS EYES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Rash generalised		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Rash		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE WENT TO THE HOSPITAL ON [redacted] WITH A BAD REACTION. HE HAD A RASH ALL OVER HIS NECK AND FACE AND BROWN CIRCLES AROUND HIS EYES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dark circles under eyes		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Dark circles under eyes		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SORE SHOULDER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Shoulder soreness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Arthralgia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). The reporter is the parent.

A 17-year-old male patient received BNT162b2 (BNT162B2), on [redacted]021 as dose 1, single (Batch/Lot number: unknown) at the age of 17 years intramuscular, in left deltoid for covid-19 immunisation. The patient's relevant medical history included: "seasonal allergies" (unspecified if ongoing), notes: Onset date: childhood. The patient's concomitant medications were not reported.
The following information was reported: RASH (hospitalization), DARK CIRCLES UNDER EYES (hospitalization) all with onset [redacted]2021, outcome "unknown" and all described as "He went to the hospital on [redacted]with a bad reaction. He had a rash all over his neck and face and brown circles around his eyes"; CARDIOMEGALY (death) with onset [redacted]2021, outcome "fatal", described as "His mother found him dead on the floor next to his bed/ An autopsy showed that his son's heart was "slightly enlarged", but he could not determine with certainty the cause of death"; ARTHRALGIA (hospitalization), outcome "unknown", described as "Sore shoulder". The patient was hospitalized for rash, dark circles under eyes (start date: [redacted]021). Therapeutic measures were not taken as a result of cardiomegaly. The patient date of death was [redacted]2021. Reported cause of death: "His mother found him dead on the floor next to his bed/ An autopsy showed that his son's heart was "slightly enlarged", but he could not determine with certainty the cause of death". The autopsy was performed, and results were not provided.

Clinical course: It was reported that, the patient did not received prior vaccinations. Autopsy results included unascentrained (heart slightly enlarged). The lot number was not available/provided at time of report completion. No any family medical history was reported relevant to AEs. Relevant tests was reported as none. Upon Follow-up (23Jan2023), it was reported that the patient died 33 days after receiving the Pfizer vaccine after being assessed in hospital for a rash, sore shoulder and rings around his eyes. Autopsy determined the cause of his [redacted]2021 death as "unascertained".

Follow-up (26Apr2022): The new information received from a contactable consumer (patient's father) via SPL. Updated information included reporter's contact information, medical history, route of administration, anatomical location, treatment received ticked no for fatal event.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (23Jan2023): This is a spontaneous follow-up report received from a contactable consumer. Updated information included: new reporter added, new event added (Sore shoulder), and clinical information was added.

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.
Follow-up (24Feb2023): Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Seasonal allergy		
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)	
Comments (B.1.7.1g)			
Onset date: childhood			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Enlargement heart		
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)	
Comments (B.1.7.1g)			

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05527456 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220707 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200643847(3)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2022[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220707 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-202200643847

Other case identifiers in previous transmission? (A.1.11) Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-202200643847

Duplicate (D) / Link (L) Report number(s) (A.1.12) ()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4) MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 84 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 4 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Booster	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Booster	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label use	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label use	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DOSE 4

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Off label use		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Off label use		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)

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ATIA - 19(1)

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DOSE 4

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Booster		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Immunisation		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2022[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VACCINATION FAILURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug ineffective		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug ineffective		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2022[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

TESTED POSITIVE FOR COVID

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	COVID-19		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	COVID-19		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2022[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

ATIA - 19(1)

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Other HCP and Consumer or other non HCP).

An 84-year-old female patient received BNT162b2 (BNT162B2), as dose 1, single (Batch/Lot number: unknown), as dose 2, single (Batch/Lot number: unknown), as dose 3 (booster), single (Batch/Lot number: unknown) and as dose 4 (booster), single (Batch/Lot number: unknown) at the age of 84 years for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: COVID-19 (medically significant) with onset [redacted]2022, outcome "unknown", described as "Tested positive for covid"; DRUG INEFFECTIVE (medically significant) with onset [redacted]022, outcome "unknown", described as "Vaccination failure"; It was reported that the patient has had both covid vaccines plus two covid boosters. DEATH (death, medically significant) with onset [redacted]2022, outcome "fatal", described as "passed away"; OFF LABEL USE (death, medically significant), IMMUNISATION (death, medically significant), outcome "fatal" and all described as "Dose 4". The patient underwent the following laboratory tests and procedures: SARS-CoV-2 test: [redacted]2022) positive. The patient date of death was [redacted]2022. The reported cause of death was unknown. It was not reported if an autopsy was performed.

Clinical course: The patient's daughter called to cancel the appointment for [redacted]2022 as the patient passed away on [redacted]2022.

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.

Follow-up [redacted]2022): This is a spontaneous follow-up report received from a contactable consumer (Clinic administrative personnel). Updated information: New reporter tab#2 added. Event Death Details in Patient tab updated. New event: Unknown cause of death, booster and off label use added.

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.

Follow-up (07Jul2022): Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the information available a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
202[redacted] CCYYMMDD	COVID-19 virus test	positive

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05544039 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220510 CCYYMMDD
	HC Initial Received Date:	20220510 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200677260(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220506 CCYYMMDD	20220506 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200677260

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200677260

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			32 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Stroke

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Stroke	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Stroke	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL VENOUS STROKE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Stroke

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP).

A 32-year-old male patient received BNT162b2 (COMIRNATY), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: CEREBROVASCULAR ACCIDENT (death, medically significant), outcome "fatal", described as "cerebral venous stroke". The patient date of death was unknown. Reported cause of death: "cerebral venous stroke".

Clinical information: Reporter would try to get all his thoughts together as concise as possible but he thought he would take a page from the PRIVACY and start with sharing the story of his friend PRIVACY who would be spending Mother's Day that year without her husband, Dr. PRIVACY who passed away at 32 years old of a cerebral venous stroke resulting in brain stem death following the vaccine. He took the vaccine because he was told that in taking it, he would not be able to catch covid or transmit it to his patients (he worked with children) which we all know is not true. Reporter was going to attach some images there of his two beautiful children and his family (with PRIVACY permission) and they were welcome to also watch a video she put together of his funeral. These were REAL people, they were REAL stories, and they were not getting the support or attention that they deserve. They took the shot, then when they pass, their stories are buried. PRIVACY wanted them to know that she was told for months that this was not the result of the vaccine. She was bullied, told to keep quiet, called crazy and anti vaccine all while trying to navigate the death of her husband and raise TWO CHILDREN ALONE. She also wanted them to see that it was finally being acknowledged in those medical journals after the medical community completely dismissed her! She knew, no one believed her. 'CVT after SARS-CoV-2 vaccination can be the first manifestation of a much more complex and life-threatening disorder, mimicking heparin-induced thrombocytopenia. CVT was not the only manifestation of vaccine-induced immune thrombotic thrombocytopenia, which can also occur with thrombosis in other sites. It was necessary to pay close attention to the most common thrombotic manifestations, such as stroke and myocardial infarction, among subjects with risk factors, because it could not be excluded that some of those cases were adverse effects of the vaccine. A headache, which is also a frequent symptom after vaccination, could be a manifestation of a CVT in a vaccine-induced immune thrombotic thrombocytopenia and a simple platelet count could help rule out this form. Conversely, a thrombocytopenia in patients with thrombotic manifestations of any kind within 4 weeks of vaccination (all cases reported so far have occurred within 24 days of vaccination[8], [9], [10]), should lead to a search for anti-FP4 antibodies.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Stroke

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05551653 (2)		Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221013 CCYYMMDD	
	HC Initial Received Date:	2022 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

FR-AstraZeneca-2022A182602()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220509 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20221010 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**	
	Company number (A.1.10.2) FR-AstraZeneca-2022A182602	

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) Health Canada MC Canada MC Canada MC Canada AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B 05590467 [redacted] FR-AstraZeneca-2022A182602

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

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Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		

Date of birth (B.1.2.1)	Age group (B.1.2.3)	Onset Age (B.1.2.2)
		57 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack
26.0	Myocardial infarction

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MY NEIGHBOR ACROSS THE STREET DIED OF A HEART ATTACK LESS THAN 24 HOURS AFTER HIS ASTRAZENECA VACCINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MYOCARDIAL INFARCTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Myocardial infarction		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the consumer via regulatory authority in Canada (Health Canada), concerning a 57 year old male patient of Unknown ethnic origin.

No medical history and concomitant products were reported.

On an unknown date, the patient received unknown dose of Vaxzevria Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for product used for unknown indication.

On an unknown date, the patient experienced my neighbor across the street died of a heart attack less than 24 hours after his astrazeneca vaccine (preferred term: Myocardial infarction), and myocardial infarction (preferred term: Myocardial infarction).

It was unknown if any action was taken with Vaxzevria Vial Contains 10 Doses Of 0.5ml.

On an unspecified date, the patient died from the event of my neighbor across the street died of a heart attack less than 24 hours after his astrazeneca vaccine and myocardial infarction.

An autopsy was not performed. The cause of death was my neighbor across the street died of a heart attack less than 24 hours after his astrazeneca vaccine and myocardial infarction.

The reporter assessed the events my neighbor across the street died of a heart attack less than 24 hours after his astrazeneca vaccine and myocardial infarction to be serious due to seriousness criteria of death and important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Corrected report on 24-May-2022: Country of case and country of reporter changed to Canada from France. Narrative amended

Summary of follow up information received by AstraZeneca/MedImmune on 10-Oct-2022 from consumer via spontaneous source: new event myocardial infarction added, new reference reporters and new RA reporter added, suspect verbatim updated from ASTRAZENECA VACCINE (UNIDENTIFIED ASTRAZENECA PRODUCT) to VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML, identified duplicates and added associated case IDs added, Narrative amended.CAUSE OF DEATH: MY NEIGHBOR ACROSS THE STREET DIED OF A HEART ATTACK LESS THAN 24 HOURS AFTER HIS ASTRAZENECA VACCINE CAUSE OF DEATH: MYOCARDIAL INFARCTION
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Myocardial infarction [reported twice as MY NEIGHBOR ACROSS THE STREET DIED OF A HEART ATTACK LESS THAN 24 HOURS AFTER HIS ASTRAZENECA VACCINE and MYOCARDIAL INFARCTION) is not listed in the company core data sheet of AZD1222. Cause of death was reported as My neighbor across the street died of a heart attack less than 24 hours after his astrazeneca vaccine and myocardial infarction. Due to limited information on relevant medical and family history, date of vaccination, event onset date, concomitant medications, autopsy details, possible risk factors (high blood pressure, smoking, stress, physical inactivity), detailed diagnostic and etiologic workup (physical examination and cardiac workup including imaging studies), the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Heart attack		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Myocardial infarction		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
PRIVACY

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
PRIVACY	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
PRIVACY	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	Health Canada

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05565966 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220517 CCYYMMDD
	HC Initial Received Date:	20220517 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200720100(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220513 CCYYMMDD	20220513 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200720100

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200720100

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05565966 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Stroke

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Stroke	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Stroke	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

STROKE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Stroke
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team.

A male patient received BNT162b2 (COMIRNATY), as dose 3 (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (DOSE 1; MANUFACTURER UNKNOWN), for Covid-19 immunisation; Covid-19 vaccine (DOSE 2; MANUFACTURER UNKNOWN), for Covid-19 immunisation.
The following information was reported: CEREBROVASCULAR ACCIDENT (death, medically significant), outcome "fatal", described as "stroke". The patient date of death was unknown. Reported cause of death: "stroke". It was not reported if an autopsy was performed. Clinical course: Reporter was unvaccinated and perfectly healthy for the last past 2 years. Reporter's brother-in-law was vaccinated and he got quiet sick for a week. His family that was living with him are all unvaccinated. They were fine. Their neighbors all got Covid and they all had their COVID Vaccine. She know in assisting home care. the employees have informed her after the third shot all the seniors are sick, with heart problems and clots. They reported 10 deaths in the last months. Why hasn't it stopped. Pfizer vaccine doesn't work. In reporter's family she had 3 deaths, one from a health attack, the second one from a clot and the third one from a stroke, they had in common they all had the booster dose. One of them was 30 years old. Reporter asking Pfizer just release their safety data full of 9 pages. Why did they not release it earlier. The data was available since February 2021. They also said they will take 75 years to release the safety data. She want to know why. It says in your document, 12 223 deaths have occurred in 3 months. That's insane. She stated Pfizer are participating in a genocide. It says on the 18 000 long pages long document to not administer the vaccine to pregnant and breastfeeding women. Why Pfizer are recommending it to pregnant women. Pfizer guys are jabbing babies and kids. Why was there no transparency. Why did Pfizer guys hide the safety data from them. Does Pfizer understand how serious this was. This was crime against humanity. She told Pfizer know what Pfizer are participating in. Pfizer will be punished by death. There was serious punishment. All the doctors, nurses will get caught. Kids are getting myocarditis and hepatitis from Pfizer vaccine. Seniors have clots and strokes. She still can't fly because I'm not vaccinated. Covid has 99.67 % survival rate. Reporter's friend was better in less then a week. The little pill was also hurting people. Caller didn't specify if she was referring to Paxlovid. Caller sister works in a hospital and she seen the number of mischarges skyrocketed. Pfizer vaccine doesn't work.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Stroke	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0 26.0	COVID-19 immunisation COVID-19 immunisation

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05565987 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220622 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200713489(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220515 CCYYMMDD	20220622 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-PFIZER INC-202200713489

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200713489

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			70 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05565987 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
418 Hours	418 Hours	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clostridium difficile infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Clostridium difficile infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
418 Hours	418 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

C-DIFFICILE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clostridium difficile infection		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Clostridium difficile infection		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

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Canada Vigilance AER#:	E2B_05565987 (1)	Page#4

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). The reporter is the patient.

A 70-year-old female patient received BNT162b2 (BNT162B2), on [redacted]2021 at 14:00 as dose 2, single (Batch/Lot number: unknown) at the age of 70 years for covid-19 immunisation. The patient's relevant medical history included: "She had C-Difficile that was it but was of healthy weight and hydrated." (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: BNT162b2 (Dose Number: 1, Batch/Lot No: Unknown, Unable to locate or read the details, Vaccine Administration Time: 02:00 PM), administration date: [redacted]2021.
The following information was reported: DEATH (death, medically significant) with onset [redacted]2021, outcome "fatal", described as "died"; CLOSTRIDIUM DIFFICILE INFECTION (medically significant), outcome "not recovered", described as "C-Difficile". Therapeutic measures were not taken as a result of death. Therapeutic measures were taken as a result of clostridium difficile infection. The patient date of death was [redacted]2021. The reported cause of death was unknown. It was not reported if an autopsy was performed. Clinical course: The patient was not received any other vaccines within 4 weeks prior to the COVID vaccine. Patient was not diagnosed with COVID-19 , Prior to vaccination. Since the vaccination the patient was not tested for COVID-19. It was not reported if an autopsy was performed.

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.

Follow-up (22Jun2022): Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clostridioides difficile infection	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)		
BNT162B2		
Start date (B.1.8c)		**End date** (B.1.8e)
2021[redacted] CCYYMMDD		202[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)		**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)		**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)		Medical history (B.1.10.7.1a.2)
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)		**Project No**
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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HC-SC REC'D 16-FE-2021

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A.1 - Type of report* [see Options]	Initial
A.3 - Organization File No. [100AN]	[redacted]
A.4 - Date report submitted [YYYY-MM-DD]	2021-02-16
A.5 - Documentation date* [YYYY-MM-DD]	[redacted]2021
A.6b -Last name* [35AN]	[redacted]
A.7.a - Phone no.* [14N]	[redacted]
A.7.a- ext. [5N]	
A.7.b - Email [100AN]	[redacted]
A.8 - Organization name* [120AN]	[redacted]
A.10 - Heath Canada institutional ID (If ID provided, no need to provide address) [9AN]	[redacted]
A.12 - City [40AN]	[redacted]
A.13 - Province/Territory [see Options]	[redacted]
A.15.a - Reason for seriousness: Death* [see Options]	Life-threatening
B.2 - Sex [see Options]**	Female
B.3.b - Age unit [see Options]**	84 years
B.6 - Known medical conditions and relevant lifestyle factors* [1500AN]	RESIDENT HAS HISTORY OF COPD

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B.7 - Known allergies* [500AN]	RESIDENT ALLERGY ON RECORD IS ONLY CODEINE
C.1 - Did the patient recover?* [see Options]	Not recovered
C.2 - Reaction start date* [YYYY-MM-DD]	[redacted]-2021
C.3 - Reaction end date* [YYYY-MM-DD]	[redacted]2021
C.4 - Description of the serious adverse drug reaction(s) [200N]**	RESIDENT RECEIVED COVID-19 VACCINE [redacted]2021 AT 1022 HOURS. RESIDENT HAD STABLE VITAL SIGNS AND NO TOTED PHYSICAL REACTION THE FOLLOWING EVENING AND NIGHTSHIFT. AT APPROX 0820 HOURS OF [redacted]2020, HCA NOTED THAT RESIDENT IS HAVING LABORED BREATHING (STRIDOR) AND ERYTHEMA AT LEFT UPPER CHEST ADJACENT TO LEFT UPPER ARM INJECTION SITE. MD WAS CONTACTED AND NP ASSESSED RESIDENT ON SITE. EPINEPHRINE AND BENADRYL GIVEN IM AS ORDERED WITH MINMAL TO NO EFFECT. RESIDENT LATER THEN PLACED ON EOL ORDERS AS FAMILY HAS WISHED. RESIDENT IS ON COMFORT CARE.
D.1 - Drug identification number (DIN)* [35AN]	
D.2 - Identifying code for urgent public health need drugs (if applicable) [35AN]**	
D.3 - Brand name (per product label) [70AN]**	Covid-19 Vaccine(PFIZER BIONTECH)
D.6 - Dose unit [see Options]	0.3 ML
D7 - Frequency [100AN]	ONCE
D.9 - Route of administration [see Options]	po
D.12 - Indication [250AN]	COVID-19 IMMUNIZATION
D.13 - Lot no. [35AN]	
D.14 - Expiry date [YYYY-MM-DD]	

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D.16 - What action was t aken? [see Options]	Not Applicable
D.17 - Did the reaction stop if dose was reduced or removed? [see Options]	Not Applicable
D.18 - Did the reaction return with reintroduction of the product? [see Options]	Not Applicable
E - Known therapeutic products taken or used at the same time the reaction occurred* [2000AN]	
F.1 - Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to assessment of the serious adverse drug reaction(s). [18000AN]	
F.2 - "Mandatory" or "Voluntary" report	Mandatory

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: Seguin, Michelle (HC/SC)
Sent: 2021-02-18 3:38 PM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC); Eng, Kathleen (HC/SC)
Subject: Health Canada Follow-Up Clarification Request

EXTERNAL

Good afternoon,

Re: Health Canada Follow-Up Clarification Request

We are contacting you today regarding an adverse event following immunization (AEFI) report submitted on your behalf to the Canada Vigilance Program on February 16, 2021.

As the result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified that clarification is required for this individual case safety report (ICSR) in order to complete the case evaluation.

Organization File No.	Canada Vigilance Case Number	Clarification Requested
[redacted]	000939409	Would you kindly have any information of the following: o At the time of the report, it is mentioned that the patient was placed on End of Life and Comfort Care. The outcome at the time of reporting was reported as "Not Recovered". Would you have any information regarding the final outcome for this patient? o If the AEFI resulted in a fatal outcome, could you please provide date of death. Any additional information that you might have would be most appreciated.

May you please kindly respond to both myself, Michelle Séguin: michelle.seguin@canada.ca in addition to the Canada Vigilance COVID-19 Vaccine generic account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca).

Or, if you prefer, you may either fax the requested information to the Canada Vigilance Program fax at 1-866-678-6789 or via sFTP (secure file transfer protocol) as you did for the initial case; please cite the Canada Vigilance **case number 000939409** if replying by either means.

If you require further information within the scope of this request, please do not hesitate to contact me.
Sincerely,

Michelle Séguin on behalf of:
The Canada Vigilance Program

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Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 866-6424
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

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[redacted]

Date	Initial
JAN 29/21	[redacted]

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

I. CLIENT IDENTIFICATION

1. LAST NAME	2. FIRST NAME
[redacted]	[redacted]

3. DATE OF BIRTH	4. SEX	5. HEALTH NUMBER
1936 [redacted] (YYYY - MM - DD)	◉ FEMALE ○ MALE ○ OTHER	[redacted] (9 DIGITS)

6. ADDRESS

[redacted]

7. POSTAL CODE	8. PROVINCE / TERRITORY	9. PHONE	EXT. #
[redacted] (A#A #A#)	[redacted]	[redacted] (###-###-####)	

II. REPORTER INFORMATION

10. SETTING
○ PHYSICIAN OFFICE ◉ PUBLIC HEALTH ○ HOSPITAL ○ PHARMACY ◉ OTHER

11. LAST NAME	12. FIRST NAME
[redacted]	[redacted]

13. ADDRESS	14. POSTAL CODE
[redacted]	[redacted] (A#A #A#)

15. PROVINCE / TERRITORY	16. PHONE	EXT. #	17. FAX
[redacted]	[redacted] (###-###-####)		[redacted] (###-###-####)

18. DATE REPORTED	19. SIGNATURE	
2021 [redacted] (YYYY - MM - DD)		○ MD ◉ RN ○ IMPACT ○ OTHER (SPECIFY):

III. SOURCE OF INFORMATION

◉ SAME AS REPORTER ○ CLIENT ○ OTHER (SPECIFY BELOW)

20. LAST NAME	21. FIRST NAME	22. RELATIONSHIP TO CLIENT

23. ADDRESS	MHSAL USE ONLY

24. POSTAL CODE (A#A #A#)	25. PROVINCE / TERRITORY

26. PHONE	EXT. #

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UNIQUE EPISODE NUMBER | IMPACT LIN

IV. INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET

27. PROVINCE / TERRITORY OF IMMUNIZATION

[redacted]

28. DATE VACCINE ADMINISTERED
2021[redacted]
(YYYY - MM - DD)

29. TIME VACCINE ADMINISTERED per pnims
~~10:02~~ ~~1022~~ 0904h → (●) AM ( ) PM
(##:##)

IMMUNIZING AGENT	TRADE NAME	MANUFACTURER	LOT NUMBER	DOSE #	DOSAGE	UNIT	SITE	ROUTE
Covid-19Vaccine		Pfizer	EK4245	1	0.3	ml	LDell	IM

30. DID AN AEFI FOLLOW A PREVIOUS DOSE OF ANY OF THE ABOVE IMMUNIZING AGENTS?
( ) NO (●) NO PRIOR DOSES ( ) UNKNOWN ( ) YES, PROVIDE DETAILS IN BOX 31.

31. ADDITIONAL DETAILS (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

32. DID THIS AEFI FOLLOW AN INCORRECT IMMUNIZATION?
(●) NO ( ) UNKNOWN ( ) YES (IF YES, CHOOSE ALL THAT APPLY AND PROVIDE DETAILS IN BOX 33)

- [ ] GIVEN OUTSIDE THE RECOMMENDED AGE LIMITS
- [ ] INCORRECT ROUTE
- [ ] PRODUCT EXPIRED
- [ ] DOSE EXCEEDED THAT RECOMMENDED FOR AGE
- [ ] WRONG VACCINE GIVEN
- [ ] OTHER (SPECIFY):

33. ADDITIONAL DETAILS (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

34. MEDICAL HISTORY UP TO THE TIME OF AEFI ONSET (CHOOSE ALL THAT APPLY AND PROVIDE DETAILS IN BOX 35)
- [ ] CONCOMITANT MEDICATION(S)
- [ ] KNOWN MEDICAL CONDITIONS / ALLERGIES
- [ ] ACUTE ILLNESS / INJURY

35. ADDITIONAL DETAILS (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)
Only Allergy noted in history is Codeine

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[redacted]

UNIQUE EPISODE NUMBER	IMPACT LIN

[redacted]

V. AEFI DETAILS

V.1. LOCAL REACTION AT OR NEAR VACCINATION SITE

36. ONSET	(MINUTES)	(HOURS)	(DAYS)	FROM IMMUNIZATION TO ONSET OF 1ST SYMPTOM OR SIGN	☐ UNRESOLVED
37. DURATION	(MINUTES)	(HOURS)	(DAYS)	FROM ONSET OF 1ST SYMPTOM / SIGN TO RESOLUTION OF ALL SYMPTOMS / SIGNS	

☐ INFECTED ABSCESS ☐ STERILE ABSCESS ☐ CELLULITIS ☐ NODULE
☐ REACTION CROSSES JOINT ☐ LYMPHADENITIS ☐ OTHER, (SPECIFY):

38. ADDITIONAL DETAILS (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

39. FOR ANY INJECTION SITE REACTION INDICATED ABOVE, CHECK ALL THAT APPLY BELOW AND PROVIDE DETAILS IN THE COMMENTS AREA IN BOX 40.

☐ SWELLING ☐ PAIN ☐ TENDERNESS ☐ ERYTHEMA ☐ WARMTH ☐ INDURATION ☐ RASH

☐ LARGEST DIAMETER OF VACCINATION SITE REACTION (SPECIFY): → (OM) ☐ SITE(S) OF REACTION (SPECIFY): → (e.g., LA, RA)

☐ PALPABLE FLUCTUANCE ☐ FLUID COLLECTION SHOWN BY IMAGING TECHNIQUE (E.G., MRI, CT, ULTRASOUND)
☐ SPONTANEOUS/SURGICAL DRAINAGE ☐ MICROBIAL RESULTS ☐ LYMPHANGITIC STREAKING ☐ REGIONAL LYMPHADENOPATHY

40. ADDITIONAL DETAILS (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

V.2. ANAPHYLAXIS OR OTHER ALLERGIC EVENTS

41. ONSET	(MINUTES)	22 (HOURS)	(DAYS)	FROM IMMUNIZATION TO ONSET OF 1ST SYMPTOM OR SIGN	☐ UNRESOLVED
42. DURATION	(MINUTES)	1 (HOURS)	(DAYS)	FROM ONSET OF 1ST SYMPTOM / SIGN TO RESOLUTION OF ALL SYMPTOMS / SIGNS	

43. CHOOSE ONE OF THE FOLLOWING: ⦿ ANAPHYLAXIS ○ OTHER ALLERGIC EVENTS

44. ☐ SKIN / MUCOSAL	○ GENERALIZED	☐ AT INJECTION SITE ☑ NON-INJECTION SITE ☐ URTICARIA ☒ ERYTHEMA ☐ PRURITUS ☐ PRICKLE SENSATION
	○ LOCALIZED	☐ AT INJECTION SITE ☐ NON-INJECTION SITE ☐ URTICARIA ☐ ERYTHEMA ☐ PRURITUS ☐ PRICKLE SENSATION
	EYES	☐ RED ☐ ITCHY
	ANGIOEDEMA	☐ TONGUE ☐ THROAT ☐ UVULA ☐ LARYNX ☐ LIP ☐ EYELIDS ☐ LIMBS ☐ OTHER, (SPECIFY):

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l'inf[redacted]

ATIA - 19(1) [redacted]

UNIQUE EPISODE NUMBER	IMPACT LIN

[redacted]

45. ☐ CARDIO-VASCULAR	☐ MEASURED HYPOTENSION	☐ ↓ CENTRAL PULSE VOLUME	☐ CAPILLARY REFILL TIME >3 SEC	
	☐ TACHYCARDIA	☐ ↓ OR LOSS OF CONSCIOUSNESS		
46. ☑ RESPIRATORY	☐ SNEEZING	☐ RHINORRHEA	☐ HOARSE VOICE	☑ STRIDOR
	☐ DRY COUGH	☐ TACHYPNEA	☐ WHEEZING	☐ GRUNTING
	☐ CYANOSIS	☐ INDRAWING / RETRACTIONS		
	☐ SENSATION OF THROAT CLOSURE			
47. ☐ GASTROINTESTINAL	☐ DIARRHEA	☐ ABDOMINAL PAIN	☐ NAUSEA	☐ VOMITING

48. **ADDITIONAL DETAILS** (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

RESIDENT RECEIVED COVID-19 VACCINE [redacted]/21@1022.STABLE VITAL SIGNS AND NO REACTION NOTED EVE SHIFT AND NIGHTSHIFT.NOTED BY HCA AT ABOUT 0820 OF [redacted],2020 TO BE HAVING STRIDOR LASTED FOR APPROX 1 HOUR AND REDNESS AT LEFT UPPER CHEST NEAR LEFT SHOULDER BUT HAS LATER RESOLVED PRIOR END OF DAYSHIFT(COPD)

V.3. NEUROLOGIC EVENTS (ASTERISK (*) APPEARING NEXT TO A TERM INDICATES SPECIFIC EVENT THAT SHOULD BE DIAGNOSED BY A PHYSICIAN)

49. ONSET	(MINUTES)	(HOURS)	(DAYS)	FROM IMMUNIZATION TO ONSET OF 1ST SYMPTOM OR SIGN	☐ UNRESOLVED
50. DURATION	(MINUTES)	(HOURS)	(DAYS)	FROM ONSET OF 1ST SYMPTOM / SIGN TO RESOLUTION OF ALL SYMPTOMS / SIGNS	

51. ☐ SEIZURE(S) (CHECK ALL THAT APPLY)	☐ WITNESSED BY HEALTHCARE PROFESSIONAL	○ YES	○ NO	○ UNKNOWN	
	☐ SUDDEN LOSS OF CONSCIOUSNESS	○ YES	○ NO	○ UNKNOWN	
	○ FOCAL				
	○ GENERALIZED				
	[redacted] ○ TONIC	○ CLONIC	○ TONIC-CLONIC	○ ATONIC	○ ABSENCE ○ MYOCLONIC
	☐ PREVIOUS HISTORY OF SEIZURES				
	[redacted] ○ FEBRILE	○ AFEBRILE	○ UNKNOWN TYPE		
52. ☐ MENINGITIS*	53. ☐ ENCEPHALOPATHY / ENCEPHALITIS*	54. ☐ GUILLAIN-BARRE SYNDROME (GBS)*			
55. ☐ BELL'S PALSY*	56. ☐ OTHER PARALYSIS*				

57. ☐ OTHER NEUROLOGIC DIAGNOSIS* *(SPECIFY)*:

58. FOR ANY NEUROLOGIC EVENT INDICATED ABOVE, CHECK ALL THAT APPLY BELOW AND PROVIDE DETAILS IN THE COMMENTS AREA IN BOX 59.

[redacted]

☐ DEPRESSED / ALTERED LEVEL OF CONSCIOUSNESS / LETHARGY / PERSONALITY CHANGE LASTING ≥ 24HRS		☐ FOCAL OR MULTIFOCAL NEUROLOGIC SIGN(S)	
☐ FEVER (≥38.0°C)	☐ CSF ABNORMALITY	☐ EEG ABNORMALITY	☐ EMG ABNORMALITY
☐ NEUROIMAGING ABNORMALITY	☐ BRAIN / SPINAL CORD HISTOPATHOLOGIC ABNORMALITY		

59. **ADDITIONAL DETAILS** (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

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[redacted]

UNIQUE EPISODE NUMBER	IMPACT LIN

[redacted]

V.4. OTHER DEFINED EVENTS OF INTEREST (ASTERISK (*) APPEARING NEXT TO A TERM INDICATES SPECIFIC EVENT THAT SHOULD BE DIAGNOSED BY A PHYSICIAN)

60. ONSET	(MINUTES)	(HOURS)	(DAYS)	FROM IMMUNIZATION TO ONSET OF 1ST SYMPTOM OR SIGN	☐ UNRESOLVED
61. DURATION	(MINUTES)	(HOURS)	(DAYS)	FROM ONSET OF 1ST SYMPTOM / SIGN TO RESOLUTION OF ALL SYMPTOMS / SIGNS	

62. ☐ HYPOTONIC-HYPORESPONSIVE EPISODE (AGE 42 YEARS)

[redacted] ☐ LIMPNESS ☐ PALLOR / CYANOSIS ☐ ↓RESPONSIVENESS / UNRESPONSIVENESS

63. ☐ PERSISTENT CRYING (CRYING WHICH IS CONTINUOUS AND UNALTERED FOR ≥ 3HRS)

64. ☐ RASH (FOR LOCAL REACTION RASH AT INJECTION SITE PLEASE DOCUMENT IN BOX 39. FOR ALLERGIC REACTION RASH PLEASE DOCUMENT USE BOX 43 SKIN / MUCOSAL WITH ADDITIONAL DETAILS IN BOX 48)

[redacted] ○ GENERALIZED ○ LOCALIZED AT NON-INJECTION SITE

65. ☐ INTUSSUSCEPTION*

66. ☐ ARTHRITIS (CHECK ALL THAT APPLY)

[redacted] ☐ JOINT REDNESS ☐ JOINT WARM TO TOUCH ☐ JOINT SWELLING ☐ INFLAMMATORY CHANGES IN SYNOVIAL FLUID

67. ☐ PAROTITIS (PAROTID GLAND SWELLING WITH PAIN AND / OR TENDERNESS)

68. ☐ THROMBOCYTOPENIA*

[redacted] ☐ CLINICAL EVIDENCE OF BLEEDING ☐ PLATELET COUNT < 150 X 10^9/L

69. ☐ OCULO-RESPIRATORY SYNDROME (ORS) (NOTE: THIS IS DIFFERENT FROM ALLERGIC/RESPIRATORY SYMPTOMS)

[redacted] ☐ BILATERAL RED EYES ☐ COUGH ☐ WHEEZE ☐ SORE THROAT ☐ DIFFICULTY SWALLOWING

☐ DIFFICULTY BREATHING ☐ CHEST TIGHTNESS ☐ HOARSENESS ☐ FACIAL SWELLING

70. ☐ FEVER ≥ 38.0°C (NOTE: REPORT ONLY IF FEVER OCCURS IN CONJUNCTION WITH A REPORTABLE EVENT. FOR FEVER IN A NEUROLOGICAL EVENT, USE SECTION V.3.)

71. ☐ OTHER SERIOUS OR UNEXPECTED EVENT(S) NOT LISTED IN THE FORM (SPECIFY AND PROVIDE DETAILS IN COMMENTS BOX 72)

72. ADDITIONAL DETAILS (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

V.5. IMPACT OF AEFI, OUTCOME, AND LEVEL OF CARE OBTAINED

73. HIGHEST IMPACT OF AEFI (CHOOSE ONE OF THE FOLLOWING)

[redacted] ○ DID NOT INTERFERE WITH DAILY ACTIVITIES

○ INTERFERED WITH BUT DID NOT PREVENT DAILY ACTIVITIES

⊗ PREVENTED DAILY ACTIVITIES

74. OUTCOME AT TIME OF REPORT

[redacted] ✓ DEATH, (SPECIFY DATE): 2021-[redacted] (YYYY - MM - DD)

○ FULLY RECOVERED

○ PERMANENT DISABILITY / INCAPACITY

N/A ⊗ NOT YET RECOVERED

○ UNKNOWN

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IN (DUE DATE) (DAYS)	IMPACT LIN

76. **HIGHEST LEVEL OF CARE REQUIRED** (CHOOSE ONE OF THE FOLLOWING)

○ EMERGENCY VISIT ○ NON-URGENT VISIT ○ NONE ○ UNKNOWN

◉ TELEPHONE ADVICE FROM A HEALTH PROFESSIONAL

○ REQUIRED HOSPITALIZATION FOR:	(DAYS)	OR	○ RESULTED IN PROLONGATION OF EXISTING HOSPITALIZATION BY:	(DAYS)

75. DATE OF HOSPITAL ADMISSION	77. DATE OF HOSPITAL DISCHARGE
(YYYY - MM - DD)	(YYYY - MM - DD)

78. **TREATMENT RECEIVED** ○ NO ○ UNKNOWN ◉ YES (IF YES, PROVIDE DETAILS OF ALL TREATMENTS INCLUDING SELF-TREATMENT IN BOX 79)

79. **ADDITIONAL DETAILS** (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

RESIDENT RECEIVED TELEPHONE ORDER FROM MD TO ADMINISTER EPINEPHRINE AND BENADRYL AS PER STANDING ORDER(ADMINISTERED). SEEN BY NP ON SITE AND EOL ORDERS IN PLACE AS PER FAMILIES WISH AS RESIDENT ON COMFORT CARE. (RESIDENT HAS CHRONIC COPD)

V.6. PUBLIC HEALTH RECOMMENDATIONS (MUST BE COMPLETED BY A MEDICAL OFFICER OF HEALTH)

☐ NO CHANGE TO IMMUNIZATION SCHEDULE	☐ EXPERT REFERRAL (SPECIFY IN BOX 70)
☐ DETERMINE PROTECTIVE ANTIBODY LEVEL	☐ CONTROLLED SETTING FOR NEXT IMMUNIZATION
☐ NO FURTHER IMMUNIZATIONS WITH (SPECIFY IN BOX 80)	☐ ACTIVE FOLLOW UP FOR AEFI RECURRENCE AFTER NEXT VACCINE
☐ OTHER (SPECIFY IN BOX 80)	☐ NO RECOMMENDATIONS

80. **COMMENTS** (ATTACH FURTHER COMMENTS ON A SEPARATE SHEET AND REFERENCE THIS BOX NUMBER)

81. LAST NAME	82. FIRST NAME	83. PHONE (###-###-####)	EXT. # (####)

84. DATE (YYYY - MM - DD)	85. SIGNATURE

ASTERISK (*) APPEARING NEXT TO A TERM INDICATES SPECIFIC EVENT THAT SHOULD BE DIAGNOSED BY A PHYSICIAN.

PLEASE SUBMIT A COPY OF ALL AEFI REPORTS BY SECURED FAX OR COURIER TO THE MEDICAL OFFICER OF HEALTH (MOH) IN YOUR REGIONAL HEALTH AUTHORITY (RHA). PLEASE CHECK OUR WEBSITE FOR UP TO DATE CONTACT INFORMATION:

[redacted]

AFTER HOURS EMERGENCY PHONE FOR PUBLIC HEALTH ISSUES: [redacted]

[redacted]

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Public Health Recommendations

AEFI Status:
Review complete

Last Review Date:
2021 Feb 08

Eligible for reporting to PHAC

Reviewer On behalf of Health Service Provider:
[redacted]

Public Health Recommendations

Add | Delete

			Date	Comments	Recorded By
○	●		2021 [redacted]	clinical course of patient meet criteria for anaphylaxis Brighton Level 1 diagnostic certainty see supplemental information from conversation with attending physician consider a causality assessment	[redacted]

Public Health Recommendations	Details
Other, specify	causality assesment

Total: 1

10

Feb. 17. 2021 8:37AM P. 8

Feb. 19. 2021 10:52AM

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[redacted]

Supplementary Information Comments

202[redacted]08:45[redacted]

[redacted] 2020 CDC [redacted] spoke to [redacted] who had filled out the AEFI for: [redacted] Medical HX: Include COPD and hx of MI prior to coming to [redacted] 2018 Allergy to Codeine Resident was on Comfort Care No previous dx of Covid No hx of contact to Covid Case No hx of anaphylaxis noted to other immunizations or other meds that [redacted] was aware of during clients stay since 2018 [redacted] was immunized on [redacted] per phims entry. Prior to immunization resident per [redacted] had no reports of concern Vitals day of immunization [redacted] 2021: Temp 36.1 Pulse 75 Resp 18 B/P 126/71 Post immunizations standard dose of Tylenol ordered for all residents 500mg. (dose given at [redacted] 2021) No concerns on evening or night shift vitals stable. On [redacted] 2021 approximately between [redacted] erythema noted to left chest and stridor noted when resident moved to chair. They moved resident back to bed. Nurse Practitioner happened to be on unit [redacted] and ordered epinephrine 0.3ml administered x1 and Benadryl 1 mg at [redacted] Vitals Post epinephrine and Benadryl: Temp 36.7 HR 125 Resp 28 B/P 118/58 O2 sat 85% O2 administered at 2L stat increased to 91% NP indicated that Resident was tachypnea/tachycardia/ no response to verbal stimuli, tactile response yes squeezed hand, no cyanosis noted ? delayed reaction ? pneumatic process ? COPD End of life Care ordered at [redacted] 2020 [redacted] Standard End of Life Care medication was ordered: Morphine (given at [redacted] 2021 at [redacted] 2.50mg Hydromorphone given [redacted] 2021 at [redacted] 0.25mg Scopolamine administered [redacted] 2021 at [redacted] 0.6mg The symptoms of stridor resolved in 1 hour. Erythema was gone by afternoon. Unsure if EOL care helped resolve [redacted] passed away [redacted] 2021 at [redacted] Case to be reviewed by MOH [redacted] [redacted] RN.BN. PNC (c) Communicable Disease Coordinator- Covid19

[redacted] 14:47 CST

[redacted] 2021 MOH call to attending Physician [redacted] and Nursing staff [redacted] at time of event Attending physician was not present. The cause of death is old age. She is unable to comment on the association with the vaccine or not but the presentation was different from the patients baseline. Pt had multiple medical problems but was stable. There is no plan for an autopsy to be done Nursing staff clarified the rapid progression of symptoms The rash was localized to the chest area and there was no rash at injection site. The respiratory symptoms progressed from audible wheeze to stridor, as pt was using accessory muscles of respiration. - [redacted]

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Medical Certificate of Death / Certificat médical de décès

ATIA - 19(1)

Vital Statistics / État civil

[redacted]

V.S. REG. NO. / Nº D'ENREG. É.C. [redacted]

NAME OF DECEASED / NOM DU (DE LA) DÉFUNT(E)

1. LA[redacted]É FAMILLE DU (DE LA) DÉFUNT(E) — 2. [redacted]

ALL GIVE[redacted]n entier)

3. AGE / ÂGE: 65

4. SEX / SEXE: ☐ MALE / MASCULIN ☑ FEMALE / FÉMININ

PLACE OF DEATH / LIEU DU DÉCÈS

5. NA[redacted] diquer le lieu exact du décès s'il n'est pas survenu dans un hôpital)

CITY, [redacted]ip, range or L.G.D.) / VILLE, VILLAGE, MUNICIPALITÉ RURALE (section, township, rang ou D.A.L.)

TO BE COMPLETED BY ATTENDING PHYSICIAN WITHIN 48 HOURS FROM DATE OF DEATH. / NOTE: BURIAL OR OTHER DISPOSITION CANNOT OCCUR BEFORE MEDICAL CERTIFICATE IS COMPLETED.
À REMPLIR PAR LE MÉDECIN TRAITANT DANS LES 48 HEURES QUI SUIVENT LE DÉCÈS. / NOTE : L'INHUMATION NE PEUT AVOIR LIEU OU LES AUTRES ARRANGEMENTS RELATIFS À LA DÉPOUILLE NE PEUVENT ÊTRE PRIS AVANT QUE LE CERTIFICAT MÉDICAL NE SOIT REMPLI.

PLEASE PRINT - DO NOT ABBREVIATE / ÉCRIRE EN CARACTÈRES D'IMPRIMERIE - NE PAS ABRÉGER

32. CAUSE OF DEATH / CAUSE DU DÉCÈS
PART I / PARTIE I

Approximate interval between onset and death. / Intervalle approximatif entre le début de la maladie ou la blessure et le décès

Disease or condition directly leading to death*. / Maladie ou état ayant mené directement au décès*.

(A) Oldage — DUE TO, OR AS A CONSEQUENCE OF / CAUSÉ PAR (OU ATTRIBUABLE À)

Antecedent causes / Morbid conditions, if any, giving rise to the above cause stating the underlying cause last. / Causes antérieures / Facteurs pathologiques, s'il y a lieu, qui ont donné naissance à la cause immédiate ci-dessus. Indiquer la cause première du décès à la fin.

(B) DUE TO, OR AS A CONSEQUENCE OF / CAUSÉ PAR (OU ATTRIBUABLE À)

(C) DUE TO, OR AS A CONSEQUENCE OF / CAUSÉ PAR (OU ATTRIBUABLE À)

(D) DUE TO, OR AS A CONSEQUENCE OF / CAUSÉ PAR (OU ATTRIBUABLE À)

* This does not mean the mode of dying e.g. heart failure, respiratory failure, it means the disease, injury, or complication that caused death.
* Il ne s'agit pas de la façon dont la personne est décédée (p. ex., insuffisance cardiaque ou respiratoire), mais plutôt de la maladie, des blessures ou des complications qui ont causé le décès.

PART II / PARTIE II

Other significant conditions contributing to the death, but not related to the disease or condition causing it. / Autres facteurs importants ayant contribué au décès, mais n'étant pas liés à la cause immédiate indiquée ci-dessus.

33. AUTOPSY / AUTOPSIE: ☐ YES / OUI ☑ NO / NON

34. IF "YES" DOES THE CAUSE OF DEATH STATED ABOVE TAKE ACCOUNT OF AUTOPSY FINDINGS? / SI OUI, LA CAUSE DU DÉCÈS SUSMENTIONNÉE TIENT-ELLE COMPTE DES RÉSULTATS DE L'AUTOPSIE? ☐ YES / OUI ☐ NO / NON

35. MAY FURTHER INFORMATION RELATING TO THE CAUSE OF DEATH BE AVAILABLE LATER? / D'AUTRES RENSEIGNEMENTS SUR LA CAUSE DU DÉCÈS POURRONT-ILS ÊTRE FOURNIS ULTÉRIEUREMENT? ☐ YES / OUI ☑ NO / NON

36. MANNER OF DEATH / CAUSE DU DÉCÈS (FOR M.E. ONLY / RÉSERVÉ AU MÉDECIN LÉGISTE)
☑ NATURAL / MORT NATURELLE ☐ SUICIDE ☐ ACCIDENT ☐ HOMICIDE ☐ PENDING INVESTIGATION / ENQUÊTE EN COURS ☐ UNDETERMINED, NON DÉTERMINÉE

37. PLACE OF INJURY (HOME, FARM, HIGHWAY, ETC.) / LIEU DE L'ACCIDENT (DOMICILE, FERME, ROUTE, ETC.)

38. TIME AND DATE OF INJURY / HEURE ET DATE DE L'ACCIDENT — TIME / HEURE | MONTH / MOIS | DAY / JOUR | YEAR / ANNÉE

39. HOW DID THE INJURY OCCUR? (DESCRIBE CIRCUMSTANCES) / CAUSE DE L'ACCIDENT (FOURNIR LES DÉTAILS)

40. IF DECEASED A WOMAN: DID THE DEATH OCCUR DURING OR WITHIN 1 YEAR OF PREGNANCY TERMINATION? / SI LA PERSONNE DÉCÉDÉE EST UNE FEMME, LE DÉCÈS EST-IL SURVENU PENDANT LA GROSSESSE OU DANS L'ANNÉE SUIVANT CELLE-CI? ☐ YES / OUI ☑ NO / NON
IF "YES" DID DEATH OCCUR: / SI OUI, LE DÉCÈS EST-IL SURVENU
A. ☐ DURING PREGNANCY / PENDANT LA GROSSESSE?
B. ☐ WITHIN 42 DAYS THEREAFTER / DANS LES 42 JOURS SUIVANT LA FIN DE LA GROSSESSE?
C. ☐ BETWEEN 43 DAYS AND A YEAR THEREAFTER / ENTRE 43 JOURS ET UN AN APRÈS LA FIN DE LA GROSSESSE?

41. WAS THERE A SURGICAL OPERATION? / Y A-T-IL EU UNE INTERVENTION CHIRURGICALE? ☐ YES / OUI ☑ NO / NON

42. IF "YES", GIVE DATE OF OPERATION / SI OUI, DATE DE L'INTERVENTION — MONTH / MOIS | DAY / JOUR | YEAR / ANNÉE

43. OPERATIVE FINDINGS / RÉSULTATS DE L'INTERVENTION

44. I CERTIFY THAT THE ABOVE NAMED PERSON DIED ON THE DATE AND FROM THE CAUSES STATED HEREIN. / J'ATTESTE QUE LE D[redacted]PERSONNE SUSNOMMÉE EST SURVENU À LA DATE INDIQUÉE CI-DESSU[redacted]RIBUABLE AUX CAUSES SUSMENTIONNÉES.

☑ PHYSICIAN / MÉDECIN
☐ MEDICAL EXAMINER / MÉDECIN LÉGISTE
☐ DELEGATE OF CHIEF MEDICAL EXAMINER / REPRÉSENTANT DU MÉDECIN LÉGISTE EN CHEF

X [redacted] — Signature of Physic[redacted]e du médecin

DATE [redacted] 2021 — MONTH / MOIS | DAY / JOUR | YEAR / ANNÉE

PRINT NAME, ADDRESS AND TELEPHONE NO. OF PHYSICIAN / NOM, ADRESSE ET Nº DE TÉLÉPHONE DU MÉDECIN (EN CARACTÈRES D'IMPRIMERIE)

DATE OF DEATH / DATE DU DÉCÈS

30. TIME / HEURE: 1500 ☐ A.M. ☐ P.M. — HOUR(S) / HEURE(S): 85 MINUTE(S) — MONTH (BY NAME) / MOIS (EN LETTRES): [redacted] — DAY / JOUR: [redacted] — YEAR / ANNÉE: 2021

31. AUTOPSY / AUTOPSIE: ☐ YES / OUI ☐ NO / NON

H. A. TO THE BEST OF MY KNOWLEDGE AND BELIEF, THIS PERSON DIED ON THE ABOVE DATE. / À MA CONNAISSANCE, LA PERSONNE EST DÉCÉDÉE À LA [redacted] Please indica[redacted]euillez indiquer s'il s'agit : a) The actual time and date of death / de l'heure et de la date réelles du décès ☐

USE BLACK INK ONLY / ENCRE NOIRE SEULEMENT
RLY AND COMPLETE ALL ITEMS / ÉCRIRE EN CARACTÈRES D'IMPRIMERIE OU TAPER À LA MACHINE ET REMPLIR CHAQUE SECTION
THIS IS A PERMANENT LEGAL RECORD / CECI EST UN ACTE AUTHENTIQUE DÉFINITIF
under Section 14(2) of The Vital Statistics Act] / [Paragraphe 14(2) de la *Loi sur les statistiques de l'état civil*]

Feb. 19. 2021 10:53AM P. 10

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ATIA - 19(1)

FAX COVER LETTER

[redacted]

To: Health Canada

From: [redacted]

Company:

Date:Feb 19 2021

Fax #: 1-866-678-6789

Reference #:

Telephone #:

Total # of pages including Cover: 10

Subject: Canada Vigilance **case number 000939409**

Greetings,

Please see attached (Recommendation and Supplementary Information Comments from Public Health/MOH including Medical cert of Death) - last 3 pages

Thank you very much

[redacted]

The documents accompanying this transmission contain confidential information intended only for the addressee. All other recipients are prohibited from disclosing, copying, distributing or taking any action in reliance on the contents. If you have received this facsimile in error, please notify us immediately and return the original to us by regular mail.

If you do not receive all of the pages, please contact the sender.

[redacted]

[redacted]

[redacted]

ATIA - 19(1)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information [illegible]

[redacted] Birth date [redacted]/1931 [redacted] Page 1/2

[redacted]2021 Canada Vigilance Adverse Reaction Reporting Form NB

Health Canada / Santé Canada [redacted]

Canada Vigilance Adverse Reaction Reporting Form

Report of suspected adverse reactions to marketed health products in Canada

See instructions and information on adverse reaction reporting and confidentiality on Page 2.
Complete all mandatory items, marked by a *, and provide as much information as possible for the remaining items. PROTECTED WHEN COMPLETED - B"

A. Patient Information

1. Identifier [redacted]

2. Age	3. Sex*	4. Height	5. Weight
☒ Years 89 ☐ Months	☐ Male ☒ Female	165 cm last	62 kg lbs

B. Adverse Reaction

1. Outcome attributed to adverse reaction (Select all that apply)

- ☒ Death: 2021[redacted] (yyyy-mm-dd)
- ☐ Life-threatening
- ☐ Hospitalization
- ☐ Hospitalization – prolonged
- ☐ Disability
- ☐ Congenital malformation
- ☐ Required intervention to prevent damage/impairment
- ☒ Other:

2. Reaction date (yyyy-mm-dd): 2021[redacted]

3. Report date (yyyy-mm-dd): 202[redacted]

4. Describe reaction or problem*

This elderly frail woman has been in a significant state of decline. She was wheel chair bound and needed assistance with all personal care and feeding. On the day of her covid vaccination she seemed more congested than usual. After her immunization in the early afternoon she seemed to have no ill effect and she remained well over the remainder of the afternoon. She was fed her supper but then became diaphoretic and dusky then collapsed and was unresponsive. She was pronounced on scene.
I was contacted as coroner to review. Given the history of a vaccination early in the day the case was reviewed with the regional coroner and deputy chief coroner. With her advanced state of decline and family aware of her pending mortality we elected to not proceed to an autopsy in this case.

5. Relevant tests/laboratory data (including dates (yyyy-mm-dd))

hx Major Depression with ECT, Dementia, hypertension
Carotid Atherosclerosis, Hypothyroid

6. Relevant history and pre-existing medical conditions (e.g. allergies, pregnancy, smoking/alcohol use, hepatic/renal dysfunction)

amlodipino 2.5 mg 1 time daily
Eltroxin 100 mcg 1 tablet 1 time daily every day now 16/01/2016
divalproex sodium 250 mg 2 in am , one in evening
trazodone 50 mg 1 tablet every day at bedtime, PRN
Effexor XR 150 mg 1 time daily

Septra De-> hives

C. Suspected Health Product(s)

1. Name*, strength and manufacturer (if known)

#1 Moderna COVID 19 vaccine

#2

2. Dose, frequency and route used

#1	#2
0.5 cc once IM	

3. Therapy dates (or duration)

#1 From (yyyy-mm-dd) - To (yyyy-mm-dd)	#2 From (yyyy-mm-dd) - To (yyyy-mm-dd)
202[redacted] to	to

4. Indication for use

#1	#2
COVID 19	

5. Reaction abated after use stopped or dose reduced

#1	#2
☐ Yes ☐ No ☒ Does not apply	☐ Yes ☐ No ☐ Does not apply

6. Lot #

#1	#2
not known by myself	

7. Expiration

#1 (yyyy-mm-dd)	#2 (yyyy-mm-dd)

8. Reaction reappeared after reintroduction

#1	#2
☒ Yes ☐ No ☐ Does not apply	☐ Yes ☐ No ☐ Does not apply

9. Concomitant health products, excluding treatment of reaction (name, dose, frequency, route used and therapy dates (yyyy-mm-dd))

10. Treatment of reaction, including dates (yyyy-mm-dd)

D. Reporter Information

1. Name*, occupation, address, telephone number* [redacted]

2. Health professional?	3. Reported to manufacturer?
☒ Yes ☐ No	☐ Yes ☒ No

* As per the Treasury Board of Canada Secretariat Government Security Policy

A program of MedEffect™ Canada

HC Pub.: 100251 (April 2010)

[redacted]anada

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Canada Vigilance AER#:	E2B_05566006 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220517 CCYYMMDD
	HC Initial Received Date:	20220517 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200720099(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220513 CCYYMMDD	20220513 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200720099

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200720099

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05566006 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Clot blood	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Clot blood	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CLOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Clot blood

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Thrombosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team.

A male patient received BNT162b2 (COMIRNATY), as dose 3 (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: THROMBOSIS |death, medically significant), outcome "fatal", described as "clot". The patient date of death was unknown. Reported cause of death: "clot". It was not reported if an autopsy was performed.

Response: Caller then start using abusive language. Reporter have explained she needs to remain respectful. After constantly saying rot in hell, Reporter had decided to disconnect the line as she would not stop yelling over the phone. Multiple attempted were made to provide her resourceful information, but caller would not stop talking. Reporter had tried placing her on hold but she would start a different conversation. She did not have any particular question beside why dont you stop selling Pfizer COVID-19 vaccine.

For Canadian Callers: The health and safety of our Pfizer colleagues has always been and remains our main priority. Pfizer knows firsthand the important role vaccinations play for society and we feel strongly that we must set an example for others to follow. We have strongly recommended that all Canadian colleagues be vaccinated, and even set up our own vaccination clinics to provide vaccines to our employees and their families. The majority of Pfizer employees in Canada have done their part to remain safe and help stop the COVID-19 spread by getting COVID-19 vaccinations. While we have not mandated or required our employees to vaccinate, we will continue to encourage vaccination in our employee population.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_05566006 (0)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_05566006 (0)	Page#6

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05584039 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220523 CCYYMMDD
	HC Initial Received Date:	20220523 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200738107(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220519 CCYYMMDD	20220519 CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200738107

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200738107

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			79 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05584039 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	fn7934	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 4 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Booster	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Booster	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboured breathing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboured breathing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label use	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label use	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DOSE NUMBER 4

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Off label use		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Off label use		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2022 [redacted]		

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DOSE NUMBER 4

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Booster		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Immunisation		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH 9 DAYS AFTER DOSE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
9 Days	9 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOTS IN LUNGS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
4 Days	4 Days	Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LABOURED BREATHING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Laboured breathing		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
1 Days	1 Days	Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). The reporter is the patient.

A 79-year-old female patient (unknown if pregnant) received BNT162b2 (COMIRNATY), on [redacted]2022 as dose 4 (booster), single (Lot number: fn7934) at the age of 79 years, in left arm for covid-19 immunisation. The patient's relevant medical history included: "Pulmonary fibrosis" (unspecified if ongoing); "MS" (unspecified if ongoing); "Celiac" (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: comirnaty (DOSE 3 (BOOSTER), SINGLE , Batch/Lot No: ff2595, Location of injection: Arm Left), administration date: [redacted]021, for COVID-19 Immunisation; BNT162b2 (DOSE 2, SINGLE, Batch/Lot No: ew0221, Location of injection: Arm Left), administration date: 06Jun2021, for COVID-19 Immunisation; BNT162b2 (DOSE 1, SINGLE, Batch/Lot No: EP6017, Location of injection: Arm Left), administration date: [redacted]2021, for COVID-19 Immunisation.
The following information was reported: OFF LABEL USE (medically significant), IMMUNISATION (medically significant) all with onset [redacted]2022, outcome "unknown" and all described as "Dose Number 4"; DYSPNOEA (hospitalization) with onset [redacted]2022, outcome "unknown", described as "Laboured breathing"; THROMBOSIS (prolonged hospitalization, life threatening,medically significant) with onset [redacted]2022, outcome "unknown", described as "blood clots in lungs"; DEATH (death, medically significant) with onset [redacted]2022, outcome "fatal", described as "Death 9 days after dose". The patient was hospitalized for dyspnoea (start date: [redacted]022, hospitalization duration: 5 day(s)); the patient prolonged hospitalization for thrombosis (start date: [redacted]022, hospitalization duration: 5 day(s)). The events "blood clots in lungs" and "laboured breathing" required physician office visit and emergency room visit. Therapeutic measures were taken as a result of death, thrombosis. The patient date of death was [redacted]2022. The reported cause of death was unknown. It was not reported if an autopsy was performed. The patient did not received any other vaccines within four weeks prior to the covid vaccine. Treatment received for the adverse event was blood thinner. The patient was not diagnosed with covid-19 prior to vaccination. The patient was not tested for covid-19 since the vaccination.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pulmonary fibrosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	MS	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Celiac disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

BNT162B2

Start date (B.1.8c)	End date (B.1.8e)
202[redacted] CCYYMMDD 202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD 2021[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
26.0 26.0	COVID-19 immunisation COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Drug name (B.1.8a)

COMIRNATY

Start date (B.1.8c)	End date (B.1.8e)
2021[redacted] CCYYMMDD	202[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
26.0	COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05587761 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220524 CCYYMMDD
	HC Initial Received Date:	20220524 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-JNJFOC-20220425043(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-JNJFOC-20220425043

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
JNJFOC	CA-JNJFOC-20220425043

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - JANSSEN INC

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
193[redacted] CCYYMMDD	Elderly		90 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)
			[redacted]

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	COVID-19

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SIMPONI	
Active Substance names (B.4.k.2.2)		
golimumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
50 Milligram,1 every 1 (Months)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Ankylosing spondylitis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2019[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
931 Days		946 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Provide the reason why Lot Number is unknown :: Discarded Provide the reason why sample is not avai		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Arterial obstruction NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Not Related

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Arterial obstruction NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Clinical Judgement	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Clinical Judgement	Not Related

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	TOZINAMERAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	AMLODIPINE	
Active Substance names (B.4.k.2.2)		
amlodipine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
5 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19 INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	COVID-19		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	COVID-19		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No	2022[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
931 Days		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOCKED ARTERY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Arterial obstruction NOS		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Arterial occlusive disease		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This solicited report received from a health care professional via [redacted]BioAdvance REMICADE SIMPONI STELARA IMBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA concerned a 90 year old male (patient number[redacted] (local case ID#[redacted]
The patient's height, and weight were not reported. The patient's past medical history included: kidney disease, and renal failure, and concurrent conditions included: ankylosing spondyloarthritis, and other pre-existing medical conditions included: no known allergies.
The patient received combination product golimumab (solution for injection in pre-filled pen, subcutaneous, batch number: UNKNOWN) 50 mg, 1 time every 1 months from [redacted]2019 to [redacted]2022 for ankylosing spondyloarthritis. Product constituent parts included smartject (route of admin, lot, serial number, model number, UDI number, and expiration were not reported). Non-company suspect drugs included: tozinameran (form of admin, route of admin, and batch number were not reported) dose, frequency, and therapy dates were not reported for prophylaxis. The batch number was not reported and has been requested. Concomitant medications included amlodipine.
Patient reported starting to have symptoms in early April, headache, sore throat, fever, diarrhea. After a few days, shortness of breath and cough, at-home Covid test positive on[redacted]2022, patient reported never having been so sick in his life. He had his 4th Pfizer Covid vaccine[redacted]MAR-2022. He told that fortunately his cardiologist had increased his dose of amlodipine from 5 mg to 10 mg a day, because before he would have had chest pain as well, which was not the case. He told that he had a nuclear test, he couldn't remember when, which showed at least one blocked artery. He was offered an angiogram to insert a stent or increase the amlodipine dose; he opted for the second option. Laboratory data included: COVID-19 virus test (NR: not provided) positive. Upon follow up reporter received a call from the patient's wife. The patient went to hospital by ambulance on[redacted]2022. He had retrosternal pain and shortness of breath. He was admitted to the cardiac intensive care unit. The patient refused to be treated. He was fully conscious. On[redacted]2022, retrosternal pain again, which was constant. He died surrounded by his family. On[redacted]2022, the patient died from COVID-19 infection. It was unknown if an autopsy was performed.
The action taken with golimumab was not changed for blocked artery and not applicable for COVID-19 infection. The action taken with tozinameran was not applicable for COVID-19 infection and not reported for blocked artery.
The outcome of the blocked artery was not reported.
The reporter considered the causality between golimumab, and covid-19 infection as not related. The reporter did not provide a causality assessment between golimumab, and blocked artery; Company causality between golimumab, and covid-19 infection was related, and between golimumab, and blocked artery was not related.
This report was serious (Death, and Hospitalization Caused / Prolonged).

Case was reassessed as serious based on additional information was received from health care professional on [redacted]2022. The following information was updated and incorporated into the case narrative: cause of death (COVID-19 infection), past medical history(renal failure), COVID-19 infection event onset date, seriousness criteria, outcome, date of death, therapy end date, action taken for COVID-19 infection changed from dosage maintained to not applicable, reporter causality (COVID-19 infection), lab data(angiogram), narrative information.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

V1: The follow up information is an update on seriousness-COVID 19 infection reassessed as serious(fatal outcome).
COVID-19 This event(s) is labeled per RSI and is therefore considered potentially related

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2022[redacted] CCYYMMDD	COVID-19 virus test	positive	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
positive			
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
	Angiogram		
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Renal disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	No	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Ankylosing spondylitis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Renal failure	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	No	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	COVID-19	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

no known allergies.

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Bioadvance	

Reporter street (A.2.1.2c)

[redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
BioAdvance REMICADE SIMPONI STELARA INBRUVICA ZYTIGA TREMFYA ERLEADA EPREX BALVERSA	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
[redacted]	Other studies

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05592267 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20221013 CCYYMMDD	
	HC Initial Received Date: 2022 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A195107()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220523 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20221010 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2022A195107

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC Canada MAH AER Number AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B 05139181 [redacted] 20211158511 CA-AstraZeneca-2022A195107

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) E2B_05597042

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 81 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Arthralgia
26.0	Death
26.0	Musculoskeletal discomfort
26.0	Pneumonia
26.0	Rash pruritic

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3) Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 prophylaxis
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
90 Milligram		
Dosage text (B.4.k.6)		
SOLUTION SUBCUTANEOUS90.0mg UNKNOWN		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Crohn's disease
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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RASH PRURITIC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Rash pruritic		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Rash pruritic		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MUSCULOSKELETAL DISCOMFORT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Musculoskeletal discomfort		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Musculoskeletal discomfort		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ARTHRALGIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Arthralgia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Arthralgia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a health professional via the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) concerning a male patient of Unknown ethnic origin (age 81 years).

No medical history was reported.

No concomitant products were reported.

On an unknown date, the patient received Vaxzevria Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadoxl ncov-19)) (batch number Unknown), via intramuscular route, for covid-19 prophylaxis. On an unknown date, the patient received Covid-19 Vaccine (covid-19 vaccine nrvv ad (chadoxl ncov-19)), total, via intramuscular route, for covid-19 immunisation.

On an unknown date, the patient started treatment with Stelara (ustekinumab) 90 mg, subcutaneous, for crohn's disease.

On an unknown date, the patient experienced pneumonia (preferred term: Pneumonia), rash pruritic (preferred term: Rash pruritic), musculoskeletal discomfort (preferred term: Musculoskeletal discomfort), arthralgia (preferred term: Arthralgia) and death (preferred term: Death).

It was unknown if any action was taken with Vaxzevria Vial Contains 10 Doses Of 0.5ml, Covid-19 Vaccine and Stelara.

On an unspecified date, the patient died.

It was not known whether an autopsy was performed. The cause of death was death, musculoskeletal discomfort, rash pruritic, pneumonia and arthralgia.

The reporter assessed the events of death, musculoskeletal discomfort, rash pruritic, pneumonia and arthralgia to be serious due to seriousness criteria of death, hospitalization and important medical event.

For regulatory reporting purposes, if an event was spontaneously reported, at least a reasonable possibility of a causal relationship was implied by the reporter, even if the relationship was unknown or unstated.

Summary of follow-up information received by AstraZeneca/MedImmune on 10-Oct-2022 from health professional via Spontaneous Source: Duplicate case found, Associate case Id added, New reference reporters added, reporter tab update, Suspect verbatim updated from Covid-19 vaccine astrazeneca to vaxzevria vial contains 10 doses of 0.5ml, new suspect covid-19 vaccine added, narrative amended.CAUSE OF DEATH: DEATH CAUSE OF DEATH: MUSCULOSKELETAL DISCOMFORT CAUSE OF DEATH: RASH PRURITIC CAUSE OF DEATH: PNEUMONIA CAUSE OF DEATH: ARTHRALGIA PNEUMONIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes RASH PRURITIC - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DEATH - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MUSCULOSKELETAL DISCOMFORT - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes ARTHRALGIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case report concerns 81 years old male vaccinee with reported fatal outcome (Preferred term: Death) in association with AZD1222. Fatal events of musculoskeletal discomfort, rash pruritic, pneumonia and arthralgia are not listed in the company core data sheet of AZD1222. Arthralgia and rash pruritic are listed adverse events for AZD1222, however as the events are reported with seriousness criteria of death, they are considered unlisted. The cause of death was reported as death, musculoskeletal discomfort, rash pruritic, pneumonia and arthralgia. Cosuspect ustekinumab could be considered as the confounding factor for pneumonia and arthralgia. Elderly age of the vaccinee could be considered as a risk factor for death. Due to limited information on details and circumstances surrounding the events, relevant medical history, concomitant medications, date of vaccination, event onset date, detailed diagnostic and etiologic workup, autopsy details, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Musculoskeletal discomfort	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Rash pruritic	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pneumonia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Arthralgia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Source Document: Source Document: 2022-05-23_exportPDF COVID-19 VACCINE (1)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) PRIVACY	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) CANADIAN HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) UNKNOWN	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) UNKNOWN
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Document Relea[redacted]e Access to Inform[redacted] divulg[redacted] l'infor[redacted]

FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI**

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
12 ans 3 mois	☑ Homme ☐ Femme	7 cm pi ___ po	69 kg ___ lbs ___ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

MCAS Ant. infarctus 11/06. angioplastie a. circonflexe intolérance aux statines. HBP.

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]		

4. Adresse	5. Courriel
[redacted]	

6. Langue préférée	7. Organisation (le cas échéant)
☑ français ☐ anglais	

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ☑ Médecin ☐ Pharmacien

☐ Autre professionnel de la santé (spécifier) : ___

9. Cela a-t-il été déclaré au fabricant?

☐ Oui ☑ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

☑ Décès (fournir la date) [redacted] 21
☐ Met la vie en danger
☐ Hospitalisation
☐ Prolongation d'une hospitalisation
☐ Incapacité
☐ Malformation congénitale
☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

☐ Oui ☐ Non ☐ Inconnu

☐ En cours de rétablissement (expliquer) : ___

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)
2021-[redacted]	—

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

décès subit.
n'avait pas présenté d'effets secondaires lors 2e injection
1re injection réaction mineure 3e d'injection

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
PB COVID19	code 208	Pfizer biontech

4. N° du lot	5. N° du DIN / N° du NPN
FA9091	

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
☑ Canada ☐ États-Unis ☐ Autre (spécifier) : ___	☐ Pharmacie ☐ Épicerie ☐ Internet ☑ Autre (spécifier) centre de vaccination santé publique

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021-06-28	—

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
2e dose.	—	IM.

13. Pourquoi le produit a-t-il été pris/prescrit?*

Prévention COVID.

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☐ Oui ☐ Non N/A.	☐ Oui ☐ Non ☑ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ☐ Non ☑ Ne s'applique pas	☐ Oui ☐ Non ☑ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

☐ Certain
☐ Probablement/vraisemblablement
☐ Possiblement
☐ Pas disponible / incapable de vérifier
☑ Improbable très improbable.
☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

∅

20. Tests/données de laboratoire pertinents

∅

** Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

Pub. : 150143 | Date : avril 2020

Santé Canada Health Canada

Canada

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Canada Vigilance AER#:	E2B_05597042 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220526 CCYYMMDD
	HC Initial Received Date:	20220526 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200755475(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220524 CCYYMMDD	20220524 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200755475

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_05139181 20211158511 CA-PFIZER INC-202200755475

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (1) E2B_05592267

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			81 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Arthralgia	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Musculoskeletal discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Rash pruritic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
90 Milligram		
Dosage text (B.4.k.6)		
90 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Crohn's disease
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ARTHRALGIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Arthralgia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Arthralgia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MUSCULOSKELETAL DISCOMFORT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Musculoskeletal discomfort
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Musculoskeletal discomfort

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pneumonia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RASH PRURITIC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Rash pruritic
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Rash pruritic

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

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Summary (B.5)

Case narrative (B.5.1)

NON-INTERVENTIONAL POST-MARKETING STUDY - PROTOCOL TITLE NOT AVAILABLE

This is a non-interventional study report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: E2B_05139181 (Health Canada).

An 81-year-old male patient received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) intramuscular for covid-19 immunisation; ustekinumab (STELARA), (Batch/Lot number: unknown) at 90 mg, subcutaneous for crohn's disease. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: ARTHRALGIA (death, hospitalization), outcome "fatal"; DEATH (death, hospitalization, medically significant), outcome "fatal"; MUSCULOSKELETAL DISCOMFORT (death, hospitalization), outcome "fatal"; PNEUMONIA (death, hospitalization, medically significant), outcome "fatal"; RASH PRURITIC (death, hospitalization), outcome "fatal". The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

The reporter's assessment of the causal relationship of "arthralgia", "death", "musculoskeletal discomfort", "pneumonia" and "rash pruritic" with the suspect product(s) COVID-19 Vaccine - Manufacturer Unknown was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the information in the case report, a possible causal relationship between the reported events and the suspect drug BNT162B2 cannot be completely excluded.

The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
	Other studies

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Canada Vigilance AER#:	E2B_05597042 (0)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05611972 (6)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20221111 CCYYMMDD	
	HC Initial Received Date: 2022 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-ALXN-A202204950(7)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220420 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20221107 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-ALXN-A202204950

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) ALXNEU	**Duplicate Case identifiers (A.1.11.2)** CA-ALXN-A202204950

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ALEXION PHARMACEUTICALS INC

Patient (B.1)

Patient Initial (B.1.1) [redacted]	**Sex (B.1.5)** Female	**Patient height (B.1.4)** 166 Centimeter	**Patient weight (B.1.3)** 56.25 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 63 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)** [redacted]

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ATIA - 19(1)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Ovarian cancer metastatic

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SOLIRIS SINGLE USE, 300 MG/30ML	
Active Substance names (B.4.k.2.2)		
eculizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02322285 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
900 Milligram,1 every 2 (Weeks)		
Dosage text (B.4.k.6)		
UNK, every 9 days		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Paroxysmal nocturnal haemoglobinuria
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20220502 CCYYMMDD	20121025 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		22 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood in urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood in urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood in urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood in urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood in urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood in urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported

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Canada Vigilance AER#:	E2B_05611972 (6)	
Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Unk		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)** Unknown	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a) 26.0	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)** Ovarian cancer metastatic	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Abdominal discomfort	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Abdominal discomfort	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Reported
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood in urine	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood in urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blood pressure reading low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest wall cyst	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dark urine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastroesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing frequency	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Operative bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Reported

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	IMOVANE	
Active Substance names (B.4.k.2.2)		
zopiclone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
5 Milligram		
Dosage text (B.4.k.6)		
5 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN D /00107901/	
Active Substance names (B.4.k.2.2)		
ERGOCALCIFEROL		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
1000 UI in the summer and 2000 UI in the winter		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CANCER, STAGE 4 CANCER, OVARIAN CANCER, MASS IN UTERUS, OVARIES, AND LYNPH NODES, SURGERY TO REMOVE A ACNCEROUS TUMOUR FROM ABDOMEN, OVARIAN CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Ovarian cancer metastatic		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Ovarian cancer metastatic		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	202203		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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OPERATIVE BLEEDING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Operative bleeding		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Procedural haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW HAEMOGLOBIN LEVELS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Haemoglobin low		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Haemoglobin decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHINGLES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Shingles		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Herpes zoster		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	202002		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW BLOOD PRESSURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Blood pressure reading low		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Blood pressure decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2022[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
3647 Days		Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SOME CYSTS ON CHEST WALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Chest wall cyst		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Chest wall cyst		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SLEEPING 22 HOURS A DAY, CANCER RELATED FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cancer fatigue
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cancer fatigue

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL DISCOMFORT ON AND OFF

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Abdominal discomfort
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Abdominal discomfort

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	202201		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABNORMAL LAB VALUES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Laboratory test abnormal
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Laboratory test abnormal

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD PRESENT IN URINE, BLOOD IN URINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Blood in urine
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Blood urine present

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20220524		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
3520 Days		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RESECTION OF HYPER-NEOPLASTIC NEVUS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Naevus
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**

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26.0	Melanocytic naevus		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LETHARGIC

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Lethargic		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Lethargy		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RECEIVED HER INFUSION 9 DAYS AFTER LAST INFUSION, PRESCRIBED INFUSIONS ARE EVERY 14 DAYS BUT TREATING PHYSICIAN REQUESTED PATIENT TO BE INFUSED EARLIER

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Off label dosing frequency		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Off label use		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4) 202205	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DARK URINES

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Dark urine		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Chromaturia		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NOTICED SOME MIGRATING JOINT SWELLING, LEFT ANKLE AND FOOT SWOLLEN AND HAD A ELBOW SWELLING

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Joint swelling		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Joint swelling		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4) 2021	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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OCCASIONAL GERD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Gastroesophageal reflux disease
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Gastrooesophageal reflux disease

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SLIGHTLY JAUNDICED WITH YELLOWING SKIN AND SCLERA, JAUNDICE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Jaundice
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Jaundice

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	2022[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Nausea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nausea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**

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26.0	No adverse event		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) No adverse event		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) No adverse event		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) No adverse event		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) No adverse event		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) No adverse event		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) No adverse event		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

Summary (B.5)

Case narrative (B.5.1)

This solicited case from Canada was reported by a consumer(patient) on 20-Apr-2022 and by a physician on 22-Apr-2022 (combined report) and by a nurse on 11-May-2022 (combined report), 25-May-2022, 26-May-2022 and 27-May-2022 (combined report) by a consumer (patient) and physician, by a nurse on [redacted]2022 and by the patient and nurse via company representative on [redacted]2022, [redacted]2022, [redacted]2022 and follow-up was received on [redacted]2022, [redacted]2022 (DCF response) (combined report) and [redacted]2022 from the physician and concerns a 63-year-old female patient (patient ID: [redacted]. The patient was enrolled in [redacted](Soliris), Innomar Soliris Patient Support Program.

Medical history/concurrent conditions included aplastic anemia, mitral valve prolapse, and tonsillectomy. Concomitant medications included zopiclone and ergocalciferol. Vaccination history included Bexsero, Menactra, and Neisseria Meningitis vaccine for serotype B. The patient's allergies included allergies to nuts and cats.

On 04-Oct-2012, the patient-initiated treatment with eculizumab (Soliris) at a dose of 600mg, every week, intravenously for the treatment of the paroxysmal nocturnal haemoglobinuria (PNH) until 25-Oct-2012. On 02-Nov-2012, the patient initiated a maintenance dose of 900mg, intravenous, every two weeks. The most recent dose of eculizumab administered prior to the onset of the event was not reported. The patient had a history of shingles (HERPES ZOSTER) since Feb-2020. The patient had repeated CT scans done on 15-Dec-2021 which demonstrated a new lytic area in T11 which was indicative of some degenerative changes and it demonstrated some cysts on the chest wall (CHEST WALL CYST) which have been known to the patient. She stated that last June she had her left ankle and foot swollen and then a few months after that she had a left elbow swelling. In November and December of last year (2021), she had some right elbow swelling and currently, she had some right foot and ankle swelling. The joint

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swelling tends to last for a couple of months and then usually goes away, and then she had a recurrence in other joints as described. She reported that when this happens, she finds it very hard to put shoes on over the affected ankles and the joint feels rather stiff and jelly-like. She was not feeling febrile at the time, and the joint was never hot to touch. She had consulted with her family doctor at one point and never had a joint aspirate. It was suggested that the joint swelling may be related to her COVID vaccine, as she had his second shot on 31-May-2021 before one of the joints swelled up, and had her booster on 02-Nov-2021 just before his right elbow acted up. The patient didn't have any calf swelling so there was no sign of DVT. The patient's last blood work was done on 14-Jan-2022, which indicated hemoglobin as 100 g/l (Ref: 115-165 g/l), white blood count 4.2 x 10^9/ L (Ref: 4-11 X10^9/L), and platelets 125 x 10^9/l (Ref: 150-400 x 10^9 /L), creatinine was 85 (Ref: 44-106 umol/l), and her paraprotein was down to 18 g/l now, which was interesting as it had come down from 22 as earlier it was 26 g/l in 2021. The patient's free light chain ratio was 0.06 which was stable from the previous. The patient was having some abdominal discomfort on and off (ABDOMINAL DISCOMFORT) since Jan-2022. In Mar-2022 (four weeks ago), due to abdominal discomfort, the patient had magnetic resonance imaging (MRI)) that showed a mass in her uterus, ovaries, and lymph nodes. The clinical signs and symptoms of ovarian mass, uterine mass, and abdominal discomfort included ovarian cancer (OVARIAN CANCER METASTATIC). The most recent dose of eculizumab was administered on 06-Apr-2022. The batch/lot number was 1001580, and 1001935 and the expiry date was 31-Mar-2023 and 31-May-2023. The sample for flow cytometry was taken on 18-Apr-2022 and the report came on 22-Apr-2022, the flow cytometry analysis indicated a large population of GPI-dependent RSC, granulocytes, and WBC which was consistent with the previous diagnosis of PNH. By comparison with the previous analysis which was done on 08-Nov-2021, the size of PNH clones was found to be similar. Any difference between the size of WBC and RBC clones may be due to hemolysis of clones or prior RBC transfusions. The flow cytometry analysis results were CD 15+ neutrophils 96.2 %, CD64+ monocytes 97.8 %, type 3 RBCs 54.40%, type 2 RBCs 6.30%, total GPI-deficient RBCs 60.7%. The patient received eculizumab on 02-May-2022 and the patient received her next infusion on 11-May-2022, 9 days after the last infusion, the prescribed infusions were every 14 days but the treating physician requested the patient to be infused earlier (OFF LABEL USE). The most recent dose of eculizumab administered before the onset of the events was on 11-May-2022. The batch/lot number was 1001935 and the expiry date was 31-May-2023. The patient reported that she would be going for surgery on 12-May-2022 for a total hysterectomy. A biopsy would be done at the time of surgery. The patient had surgery on 12-May-2022 to remove a cancerous tumor from her abdomen (previously reported). The patient was admitted to the hospital five days post-surgery from 12-May-2022 to 16-May-2022. She stated that she had a large mass (tumor) on the ovary adhering to the abdominal wall, bowels, appendix, bladder, and uterus. She added that she received two units of transfusion, one during surgery and one post-surgery due to low hemoglobin levels (HAEMOGLOBIN DECREASED), as a result of operative bleeding (PROCEDURAL HAEMORRHAGE). A total hysterectomy was completed and the surgeons removed as much of the tumor as possible before abandoning the surgery due to low hemoglobin. She had an occasional GERO (GASTROOESOPHAGEAL REFLUX DISEASE), and resection of hyper-neoplastic nevus (MELANOCYTIC NAEVUS). She also had some slight drifting down of hemoglobin (previously reported), and the paraprotein has unusually come down a little bit. The patient noticed in the past few months that she had some migrating joint swelling (JOINT SWELLING). The patient also had abnormal laboratory values (LABORATORY TEST ABNORMAL). On 12-May-2022, neutrophils 0.67 x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 13-May-2022 0.87 x 10^9/ L (Ref: 2-7.50 x 10^9 /L, on 14-May-2022 1.04x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 15-May-2022 0.83 x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 16-May-2022 0.83 x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 23-May-2022 1.85 x 10^9/L). On 23-May-2022, WBC count 2.8 x 10^9/L (Ref: 4-11 X10^9/L), RBC count 2.76/L (Ref: 3.5-5.5/L), lymphocytes 0.60 x 10^9/L (Ref: 1-4 x 10^9/L), monocytes 0.28 x 10^9/ L (0.3-0.8 x 10^9/ L). On 08-Nov-2021, LDH 233 u/l (Ref: 100-250 u/l), on 18-Apr-2022 331 /l (Ref: 100-250 u/l), on 12-May-2022 251 u/l (Ref: 100-250 u/l), on 14-May-2022 303 u/l (Ref: 100-250 u/l), on 14-May-2021 304 u/l (Ref: 100-250 u/l), on 15-May-2022 286 u/l (Ref: 100-250 u/l) and on 16-May-2022 277 u/l (Ref: 100-250 u/l). On 23-May-2022, albumin was 0.30 g/l, hematocrit 0.282%, haemoglobin 86 g/l (Ref: 115-165 g/l), mean corpuscular volume 102.2 fl (78-96 fl), red blood distribution width 15.5 % (Ref: 10-14.5%). On 24-May-2022, the patient went back to the emergency room due to blood present in her urines (BLOOD URINE PRESENT). The patient was assessed and infection was ruled out it was concluded that the bleeding was a result of extensive work done to the bladder during the surgical procedure. No further information was provided. The most recent dose of eculizumab administered before the onset of the events was on [redacted] 2022. The batch/lot number was 1002088 and the expiry date was 31-Mar-2024. The patient was diagnosed with Stage 4 cancer (previously reported) and is scheduled for radiation to target lymph nodes in the neck and abdomen, starting on [redacted] 2022. The patient had an appointment with the treating physician tomorrow and was also associated with the palliative care team for cancer and symptoms management. She had been lethargic (LETHARGY) and is also slightly jaundiced with yellowing skin and sclera (JAUNDICE). The patient had nausea (NAUSEA) and dark urines (CHROMATURIA). These symptoms are suspected to be related to the mass in her abdomen due to a cancer diagnosis. The most recent dose of eculizumab was administered on [redacted] 2022. The patient reported that he had four transfusions two weeks ago because of jaundice (previously reported), which was reported on [redacted] 2022. The patient was advised to go to the hospital and received transfusions due to blood in the urine (previously reported) secondary to stage 4 cancer (previously reported) it was unknown exactly where that bleeding was from. The patient also received five rounds of radiation from [redacted] 2022 to [redacted] 2022 on the left clavicle and abdomen. No further treatment was required. The events of mass, and uterine mass were upgraded to serious based on medical judgment since the events possibly required hospitalization and were possibly related to ovarian cancer. The most recent dose of eculizumab administered before the onset of the events was on [redacted] 2022. The batch/lot number was 1002194 and the expiry date was 30-Sep-2023. The most recent dose of eculizumab administered before the onset of the events was on [redacted] 2022. On [redacted] 2022 the infusion nurse reported the following blood pressure readings, pre-infusion (15:42) was 83/55 mmHg and end of infusion (16:34) was 85/56 mmHg, the patient's blood pressure was low (BLOOD PRESSURE DECREASED). The patient has been sleeping for 22 hours a day on an unspecifiefd date in 2022 with a Palliative Performance Scale score of 20% and was declining. The physician reported the diagnosis or clinical signs and symptoms are cancer related fatigue. The patient was diagnosed with stage 4 bowel cancer (GASTROINTESTINAL CANCER METASTATIC) with metastasis to the bladder, lymph nodes, liver, and multiple organs. The patient still wanted the infusion on [redacted] 2022 which will be her last appointment and the patient has chosen the date of [redacted] 2022 for medical assistance in dying (MAID), the palliative doctor will go into the patient's home to perform the procedure. The physician reported that the patient discontinued therapy as she received medical assistance and died on [redacted] 2022. Therefore, the patient deceased on [redacted] 2022. The cause of death was ovarian cancer. Upon follow-up, the physician reported that it was incorrect the patient has ovarian cancer, in lymph nodes, and metastasis to the bladder was not caused by eculizumab. Related to radiation and surgery. The diagnosis for the low blood pressure was reported as unknown. The seriousness of the events of procedural haemorrhage, ovarian cancer, death, and stage 4 bowel cancer was assessed as serious (medically significant) by Alexion as these events were included in the Important Medical Events list. No action was taken with eculizumab in response to the events. Action taken with eculizumab in response to the events of blood pressure low, sleeping 22 hours per day, and stage 4 bowel cancer, was treatment withdrawn. The action taken with eculizumab in response to the event of death was reported as not applicable. Corrective treatment for the events of ovarian mass (a symptom of ovarian cancer), uterine mass, and abdominal discomfort included surgery (hysterectomy) and for the events of haemoglobin decreased and procedural haemorrhage included two units of transfusion. Corrective treatment for the events of jaundice and blood in urine included four transfusions. Corrective treatment for the event of stage 4 cancer included five rounds of radiation

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and surgery. No treatment was required for the event of blood pressure decreased and corrective treatment for the rest of all events was not reported. The event outcome for procedural haemorrhage, chest wall cyst, was not reported and for the other events, it was not resolved. The outcome of the event blood pressure decreased was resolved. Upon the follow-up information, it was reported that the autopsy was not performed.
The reporter (patient) and nurse causality between the events of, herpes zoster, chest wall cyst, laboratory test abnormal, joint swelling, procedural haemorrhage, the patient deceased and eculizumab therapy was not reported. The reporter causality for haemoglobin decreased, and mass was reported as unknown. The causality of eculizumab treatment was unknown to the patient and the nurse. The causality with eculizumab treatment was not related to the rest of all events. The causality between the COVID-19 vaccine and the rest all the events was not reported. The alternative etiology included in the events of gastrointestinal cancer metastatic was reported as ovarian cancer, for the event of ovarian cancer was related to radiation and surgery.

No additional information has been requested as it is a data clarification form (DCF) response.

Company comment: Upon follow-up, this case is a serious, medically confirmed, solicited report of events ovarian cancer metastatic (F, H, MS), procedural haemorrhage (H, MS), haemoglobin decreased (H); non-serious, not medically confirmed events abdominal discomfort, herpes zoster, chest wall cyst, laboratory test abnormal, joint swelling, melanocytic naevus, gastrooesophageal reflux disease; non-serious, medically confirmed events off label use, blood urine present, lethargy, chromaturia, jaundice, nausea, blood pressure decreased, cancer fatigue. The events of haemoglobin decreased, gastrooesophageal reflux disease, jaundice, nausea, and joint swelling are listed in the eculizumab CCDS while the rest of the events are unlisted. Listedness is unknown for the COVID-19 vaccine. The event of joint swelling is attributed to the COVID-19 vaccine due to likely temporal association; hence considered related to the COVID-19 vaccine and not related to eculizumab; the rest of the events are not related to the COVID-19 vaccine based on the lack of temporal plausibility. There is a lack of information on the clinical details of the events, medical history, risk factors for malignancy, and causal factors for the events of ovarian cancer metastatic, abdominal discomfort, melanocytic naevus, herpes zoster, gastrooesophageal reflux disease, chest wall cyst; hence the events considered as not related to eculizumab. The event of abdominal discomfort could be secondary to ovarian cancer metastatic. Procedural haemorrhage could be due to surgery done for ovarian cancer metastatic and not related to eculizumab. The events of lethargy, chromaturia, jaundice, and nausea could most likely be attributed to the underlying ovarian cancer metastatic and PNH and not related to eculizumab. The events of haemoglobin decreased, laboratory test abnormal and blood urine present are more likely due to underlying paroxysmal nocturnal haemoglobinuria given its clinical manifestations; hence considered as not related to eculizumab. Off-label use is a non-clinical event; hence considered not related to eculizumab. The events of blood pressure decreased and cancer fatigue was likely due to ovarian cancer metastatic and associated complications; hence not related to eculizumab.

Follow-up was received on [redacted] 2022 from the physician and contained the following significant information:
Added information regarding the autopsy.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20211108 CCYYMMDD	LDH	263	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
U/L	100	250	No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
20220418 CCYYMMDD	LDH	331	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
U/L	100	250	No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
20220512 CCYYMMDD	LDH	251	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
U/L	100	250	No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
20220514 CCYYMMDD	LDH	303	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
U/L	100	250	No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
20220514 CCYYMMDD	LDH	304	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

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U/L	100	250	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20220515 CCYYMMDD	LDH	286	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
U/L	100	250	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20220516 CCYYMMDD	LDH	277	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
U/L	100	250	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20220523 CCYYMMDD	Albumin	0.30	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
g/l		less than .15	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20220523 CCYYMMDD	Haemoglobin increased	86	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
g/l	115	165	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20220523 CCYYMMDD	Hematocrit	0.282	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%	0.340	0.490	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20220523 CCYYMMDD	Mean corpuscular volume	102.2	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
fL	78	96	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20220523 CCYYMMDD	Red blood cell distribution width increased	15.5	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%	10	14.5	No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2022[redacted] CCYYMMDD	Blood pressure	83/55	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
mmHg	Not provided	Not provided	Yes

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2022[redacted] CCYYMMDD	Blood pressure	85/56	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
mmHg	Not provided	Not provided	Yes

Results of tests and procedures (B.3.2)

On 14-Jan-2022, platelets 125 x 10^9/l (Ref: 150-400 x 10^9 /L).
??-Mar-2022: MRI: a mass in her uterus, ovaries and lymph nodes.
On 12-May-2022, neutrophils 0.67 x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 13-May-2022 0.87 x 10^9/ L (Ref: 2-7.50 x 10^9 /L, on 14-May-2022 1.04x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 15-May-2022 0.83 x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 16-May-2022 0.83 x 10^9/ L (Ref: 2-7.50 x 10^9 /L), on 23-May-2022 1.85 x 10^9/L).
On 23-May-2022, WBC count 2.8 x 10^9/L (Ref: 4-11 X10^9/L), RBC count 2.76/L (Ref: 3.5-5.5/L), lymphocytes 0.60 x 10^9/L (Ref: 1-4 x 10^9/L), monocytes 0.28 x 10^9/L (0.3-0.8 x 10^9/ L).
Unspecified date: free light chain ratio was 0.06.

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Paroxysmal nocturnal haemoglobinuria	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Aplastic anemia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
20120911 CCYYMMDD	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Mitral valve prolapse	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
1970 CCYY	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Tonsillectomy	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
1964 CCYY	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Allergy to nuts	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Allergy to animal	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Ovarian cancer metastatic	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)

BEXSERO

Start date (B.1.8c)	End date (B.1.8e)
20190522	
CCYYMMDD	CCYYMMDD
20140612	
CCYYMMDD	CCYYMMDD
20140515	
CCYYMMDD	CCYYMMDD
20201230	
CCYYMMDD	CCYYMMDD

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	Immunization
26.0	Immunization
26.0	Immunization
26.0	Immunization

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)
v.26.0	No adverse event

Drug name (B.1.8a)

MENACTRA

Start date (B.1.8c)	End date (B.1.8e)
20190327	
CCYYMMDD	CCYYMMDD
20160204	
CCYYMMDD	CCYYMMDD
20120906	
CCYYMMDD	CCYYMMDD
20130829	
CCYYMMDD	CCYYMMDD
20201230	
CCYYMMDD	CCYYMMDD

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	Immunization
26.0	Immunization
26.0	Immunization
26.0	Immunization
26.0	Immunization

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)
v.26.0	No adverse event

Drug name (B.1.8a)

NEISSERIA MENINGITIDIS

Start date (B.1.8c)	End date (B.1.8e)
20121115	
CCYYMMDD	CCYYMMDD

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	Immunization

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)
v.26.0	No adverse event
v.26.0	No adverse event
v.26.0	No adverse event
v.26.0	No adverse event
v.26.0	No adverse event
v.26.0	No adverse event
v.26.0	No adverse event
v.26.0	No adverse event

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1) Innomar Soliris Patient Support Program		Project No	
Sponsor Study no. (A.2.3.2) [redacted] (Soliris)		Observed study type (A.2.3.3) Other studies	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220607 CCYYMMDD
	HC Initial Received Date:	20220607 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200803136(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220605 CCYYMMDD	20220605 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200803136

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200803136

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			9 Decade
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cancer

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021 CCYY	2021 CCYY	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer (NOS)	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer (NOS)	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Cancer (NOS)		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Neoplasm malignant		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE ABDOMINAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Abdominal pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Abdominal pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a non-contactable reporter(s) (Other HCP).

A female patient in her 80's received BNT162b2 (COMIRNATY), in 2021 as dose 3 (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (1st dose), administration date: 2021; Covid-19 vaccine (2nd dose), administration date: 2021.
The following information was reported: NEOPLASM MALIGNANT (death, medically significant), outcome "fatal", described as "Cancer"; ABDOMINAL PAIN (non-serious), outcome "unknown", described as "severe abdominal pain". The patient date of death was unknown. Reported cause of death: "Cancer".

Clinical course: : Reporter reporting this interaction based on a conversation they had with a friend at there tennis club. The patient is his girlfriend's mom. Female patient in her 80s received 3 doses of COVID-19 vaccine last year and 6 months after receiving booster shot, patient developed severe abdominal pain and died of cancer. The cancer was quick to progress and did not have time to be diagnosed or treated. Unknown if patient had any underlying health conditions or was on any other medications. Event took place after use of product. Reporter does not wish to be contacted for follow-up.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

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MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the information provided in the narrative, a causal association between the suspect drug and the events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evalustion, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cancer	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

COMIRNATY

Start date (B.1.8c)	End date (B.1.8e)
20210101 CCYYMMDD 20210101 CCYYMMDD	20210101 CCYYMMDD 20210101 CCYYMMDD
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05643205 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220613 CCYYMMDD
	HC Initial Received Date:	20220613 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200828129(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220610 CCYYMMDD	20220610 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200828129

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_05301736 20220246261 CA-PFIZER INC-202200828129

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			70 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebrovascular accident	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Drug ineffective for unapproved indication	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Fall	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Full blood count decreased	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	EPOETIN ALFA	
Active Substance names (B.4.k.2.2)		
epoetin alfa		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Anaemia of malignant disease
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBROVASCULAR ACCIDENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebrovascular accident		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebrovascular accident		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DRUG INEFFECTIVE FOR UNAPPROVED INDICATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug ineffective for unapproved indication		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug ineffective for unapproved indication		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fall		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fall		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FULL BLOOD COUNT DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Full blood count decreased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Full blood count decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

NON-INTERVENTIONAL POST-MARKETING STUDY - PROTOCOL TITLE NOT AVAILABLE

This is a non-interventional study report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: E2B_05301736 (Health Canada).

A 70-year-old male patient received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) intramuscular for covid-19 immunisation; epoetin alfa (EPOETIN ALFA), (Batch/Lot number: unknown), subcutaneous for anaemia of malignant disease. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: CEREBROVASCULAR ACCIDENT (death, hospitalization, medically significant), outcome "fatal"; DRUG INEFFECTIVE FOR UNAPPROVED INDICATION (death, hospitalization, medically significant), outcome "fatal"; FALL (death, hospitalization, medically significant), outcome "fatal"; FULL BLOOD COUNT DECREASED (death, hospitalization, medically significant), outcome "fatal".
Clinical course: The reporter's assessment of the causal relationship of "cerebrovascular accident", "drug ineffective for unapproved indication", "fall" and "full blood count decreased" with the suspect product(s) COVID-19 Vaccine - Manufacturer Unknown was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.
The action taken for epoetin alfa was unknown. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

As there is limited information in the case provided, the causal association between the reported events cerebrovascular accident and fall with the suspect drug BNT162B2 cannot be excluded. Based on the available information events drug ineffective for unapproved indication and full blood count decreased considered associated to the underlying medical condition of malignant disease and suspect product Epoetin Alfa and unrelated to BNT162B2. The case will be reassessed once new information is available.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	
	Other studies	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05643258 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220613 CCYYMMDD
	HC Initial Received Date:	20220613 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200814124(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220608 CCYYMMDD	20220612 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200814124

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada PFIZERINC	000987996 CA-PFIZER INC-202200814124

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Foetal heart rate abnormal
26.0	Maternal exposure during pregnancy

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Transplacental	**Parent route of admin (B.4.k.9)** Intramuscular
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Foetal heart rate abnormal	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Foetal heart rate abnormal	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Maternal exposure during pregnancy	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Maternal exposure during pregnancy	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MATERNAL EXPOSURE DURING PREGNANCY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Maternal exposure during pregnancy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Maternal exposure during pregnancy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FOETAL HEART RATE ABNORMAL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Foetal heart rate abnormal
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Foetal heart rate abnormal

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from Regulatory Authority. Regulatory number: 000987996 (Health Canada).

A fetus patient was exposed to COVID-19 Vaccine - Manufacturer Unknown, transplacental, administration details for the mother: as dose number unknown, single (Batch/Lot number: unknown) intramuscular for covid-19 immunisation.
The mother's relevant medical history and concomitant medications were not reported.
The following information was reported: FOETAL HEART RATE ABNORMAL (death, medically significant), outcome "fatal"; MATERNAL EXPOSURE DURING PREGNANCY (death, medically significant), outcome "fatal". The pregnancy resulted in still birth. The patient date of death was unknown. Reported cause of death: "Foetal heart rate abnormal", "Maternal exposure during pregnancy".

Follow-up attempts are completed. No further information is expected.

Amendment: This follow up is being submitted to amend previously reported information: removed event 'Foetal death'.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Maternal exposure during pregnancy	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Foetal heart rate abnormal	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05695345 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220715 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200893313(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220624 CCYYMMDD	20220714 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200893313

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200893313

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			46 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

ATIA - 19(1)

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Canada Vigilance AER#:	E2B_05695345 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	FD7206	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B.4.k.15)**
110 Days	110 Days	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dizziness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dizziness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) AMITRIPTYLINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) amitriptyline hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ROSUVASTATIN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VENTOLIN [SALBUTAMOL]	
Active Substance names (B.4.k.2.2) SALBUTAMOL		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	COVERSYL [PERINDOPRIL ARGININE]	
Active Substance names (B.4.k.2.2)		
PERINDOPRIL ARGININE		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
4 Milligram 1 (Days)		
Dosage text (B.4.k.6)		
4 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Hypertension
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
110 Days	110 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTENSE HEADACHES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
1 Days	1 Days	Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIZZINESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dizziness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dizziness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
1 Days	1 Days	Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nausea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Nausea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
1 Days	1 Days	Not recovered/not resolved	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP and Physician).

A 46-year-old male patient received BNT162b2 (COMIRNATY), on [redacted]2021 as dose 2, single (Lot number: FD7206) at the age of 46 years for covid-19 immunisation. The patient's relevant medical history included: "Allergies: Penicillin" (unspecified if ongoing); "Chronic asthma" (unspecified if ongoing), notes: Mild; "Hypertension" (unspecified if ongoing), notes: well controlled; "Dyslipidemia" (unspecified if ongoing); "Sleep apnea" (unspecified if ongoing). Concomitant medication(s) included: PMS AMITRIPTYLINE; ROSUVASTATIN; VENTOLIN [SALBUTAMOL]; COVERSYL [PERINDOPRIL ARGININE] oral taken for hypertension. Vaccination history included: Comirnaty (Dose 1; Batch/Lot No: Ex0438), for covid-19 immunisation.
The following information was reported: DIZZINESS (non-serious) with onset [redacted]2021, outcome "not recovered"; HEADACHE (non-serious) with onset [redacted]2021, outcome "not recovered", described as "Intense headaches"; NAUSEA (non-serious) with onset [redacted]2021, outcome "not recovered"; MYOCARDIAL INFARCTION (death, medically significant) with onset [redacted]2021, outcome "fatal", described as "heart attack". The event "heart attack" required emergency room visit. Therapeutic measures were not taken as a result of myocardial infarction. Therapeutic measures were taken as a result of headache, dizziness, nausea. The patient date of death was [redacted]2021. Reported cause of death: "Heart attack". No autopsy was performed.

Clinical course: The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Treatment for the events included Tylenol and Gravol. Prior to vaccination, the patient was not diagnosed with covid-19 and since the vaccination, the patient had not been tested for covid-19. As of 08Jul2022, diagnosis of heart attack according to the spouse and emergency room physician. Sudden death at home and there were no clear warning signs. Death report was completed at the emergency room. Physician indicated that she does not have the information regarding the vaccination dates. Coversyl was taken at the time of the vaccination.

Follow-up (08Jul2022): This is a spontaneous follow-up report from contactable physician. Updated information included patient details (medical history, death details updated), product details (concomitant coversyl added), and event details (unknown cause of death was updated to heart attack).

Follow-up attempts are completed. No further information is expected.

Amendment: This follow-up report is being submitted to amend previous information: Physician confirmed that no relevant test were performed for this patient.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of the reported event cannot be totally excluded.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Penicillin allergy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Asthma chronic	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
Mild		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
well controlled		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyslipidemia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Sleep apnea	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
COMIRNATY	
Start date (B.1.8c)	**End date (B.1.8e)**
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
26.0	COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Physician
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220629 CCYYMMDD
	HC Initial Received Date:	20220629 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-595968(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220627 CCYYMMDD	20220627 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2022-595968

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2022-595968

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2) elasomeran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 1 Dosage forms		
Dosage text (B.4.k.6) 1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Clot blood	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Clot blood	
Source of assessment (B.4.k.18.2) Non-Health care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) Non-Health care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CLOTTING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MASSIVE HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
48 Hours	48 Hours	Fatal	

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a non-health professional and describes the occurrence of THROMBOSIS (Clotting) and MYOCARDIAL INFARCTION (Massive heart attack) in a patient of an unknown age and gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Clotting) (seriousness criteria death and medically significant). an unknown date, the patient experienced MYOCARDIAL INFARCTION (Massive heart attack) (seriousness criteria death and medically significant). The reported cause of death was massive heart attack and clotting. It is unknown if an autopsy was performed.

No concomitant medication was reported.

Patient died of a massive heart attach 48 hours after the Moderna shot which was caused by clotting, stemming from this drug.

No treatment information was provided.

Company Comment: This spontaneous case concerns a patient (age and gender not specified) with no medical history reported, who experienced the unexpected fatal serious (medically significant) AESI of Thrombosis and Myocardial infarction unspecified days after a dose of mRNA-1273 vaccine (dose number not specified). Death occurred 48 hours after the vaccination. The reported cause of death was massive heart attack and clotting. It is unknown if an autopsy was performed. No further details on clinical course, other lab test results and treatment received were reported. The outcome of both events was reported as fatal. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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This spontaneous case concerns a patient (age and gender not specified) with no medical history reported, who experienced the unexpected fatal serious (medically significant) AESI of Thrombosis and Myocardial infarction unspecified days after a dose of mRNA-1273 vaccine (dose number not specified). Death occurred 48 hours after the vaccination. The reported cause of death was massive heart attack and clotting. It is unknown if an autopsy was performed. No further details on clinical course, other lab test results and treatment received were reported. The outcome of both events was reported as fatal. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220809 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202200920730(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220702 CCYYMMDD	20220809 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202200920730

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202200920730

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			78 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05725375 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cardiac disorder NOS
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cardiac disorder NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cardiac disorder NOS	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HER ORGANS SHOUT DOWN SLOWLY, ONE BY ONE UNTIL SHE DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THE REPORTED CAUSE OF DEATH WAS "HEART BUT REALLY >> PFIZER".

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Cardiac disorder NOS		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Cardiac disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Fatal	

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ATIA - 19(1)

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP).

A 78-year-old female patient received BNT162b2 (COMIRNATY), on [redacted]021 as dose 3 (booster), single (Batch/Lot number: unknown) at the age of 77 years, in right arm for covid-19 immunisation. The patient's relevant medical history included: "health issues/ heart" (unspecified if ongoing); "health issues/ liver" (unspecified if ongoing); "Allergy" (unspecified if ongoing). The patient took concomitant medications. Vaccination history included: biontech/pfizer vaccine (comirnaty) (Dose 2, Location of injection: Arm Right), administration date: [redacted]020, when the patient was 77-year-old, for Covid-19 immunization; biontech/pfizer vaccine (comirnaty) (Dose 1, Location of injection: Arm Right), administration date: 11Jun2019, when the patient was 75-year-old, for Covid-19 immunization.
The following information was reported: DEATH (death, hospitalization, medically significant), outcome "fatal", described as "her organs shout down slowly, one by one until she died"; CARDIAC DISORDER (death), outcome "fatal", described as "The reported cause of death was "Heart but really >> Pfizer".". The patient was hospitalized for death (hospitalization duration: 21 day(s)). The events "her organs shout down slowly, one by one until she died" and "the reported cause of death was "heart but really >> pfizer"." required emergency room visit. The patient underwent the following laboratory tests and procedures: SARS-CoV-2 test: negative. Therapeutic measures were taken as a result of death, cardiac disorder. The patient date of death was [redacted]2021. The reported cause of death was unknown, "The reported cause of death was "Heart but really >> Pfizer".". No autopsy was performed.
The clinical course: The reporter's cousin (patient) had prior health issues and lived quite well on preventive meds for 20 years with her liver and heart. She was fine until she had Pfizer, 3 shots as coerced. The reporter's cousin went into hospital and before they could start tests, she wound up in ICU for over 2 weeks as her organs shout down slowly, one by one until she died. The treatment received for the adverse event included dialysis.
Prior to vaccination, patient was not diagnosed with COVID-19. The reported cause of death was "Heart but really >> Pfizer".

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.

Follow-up (09Aug2022): Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	COVID-19 PCR test	negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart disorder	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Liver disorder	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Allergy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac disorder NOS	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

COMIRNATY

Start date (B.1.8c)	End date (B.1.8e)
202[redacted] CCYYMMDD 201[redacted] CCYYMMDD	202[redacted] CCYYMMDD 2019[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0 26.0	COVID-19 immunization COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05725375 (1)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05742627 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220928 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2022103680(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
202[redacted] CCYYMMDD	20220926 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2) CA-GLAXOSMITHKLINE-CA2022103680

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
01052547635	CA-GLAXOSMITHKLINE-CA2022103680

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04638235, (2) , (2) , (2) , (2) E2B_03837154, (2) , (2) E2B_02395154, (2) E2B_02776365, (2) , (2) , (2) E2B_01954979, (2) , (2) E2B_04638235, (2) , (2) , (2) , (2) E2B_03837154, (2) , (2) E2B_02395154, (2) E2B_02776365, (2) , (2) , (2) E2B_01954979, (2) , (2) E2B_04638235, (2) , (2) , (2) , (2) E2B_03837154, (2) , (2) E2B_02395154, (2) E2B_02776365, (2) , (2) , (2) E2B_01954979

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - GLAXOSMITHKLINE

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			77 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05742627 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	KH8X	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100mg Z every 4 weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Eosinophilic asthma
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20171220 CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
ExpDT=31-AUG-2025		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Blackout	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Blackout	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Difficulty breathing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Difficulty breathing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Low blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Low blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	FLOVENT	
Active Substance names (B.4.k.2.2)		
fluticasone propionate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK, bid, 500mcg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	GLYCOPYRRONIUM BROMIDE/INDACATEROL MALEATE	
Active Substance names (B.4.k.2.2)		
glycopyrrolate indacaterol maleate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK, qd		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) PREDNISONE	
Active Substance names (B.4.k.2.2) prednisone		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK, daily tapering		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VENTOLIN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK, qd		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ADVISED THAT HIS MOTHER (THE PATIENT) HAS PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ADMITTED TO THE HOSPITAL YESTERDAY DUE TO HER BREATHING / PATIENT WAS ADMITTED TO HOSPITAL OF [redacted] 2022

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Difficulty breathing		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT WAS ADMITTED TO HOSPITAL THE WEEK OF [redacted] 2022

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Blackout		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Loss of consciousness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT BP IS LOW (96/63)

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Low blood pressure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hypotension		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05742627 (2)	Page#10

Summary (B.5)

Case narrative (B.5.1)

This case was reported by a consumer via patient support programs and described the occurrence of death in a 77-year-old female patient who received mepolizumab powder for injection (batch number KH8X, expiry date 31st August 2025) for eosinophilic asthma.

Co-suspect products included covid-19 vaccine (Covid Vaccine) for drug use for unknown indication.

Additional subject notes included no other condition. Concomitant products included fluticasone propionate (Flovent), glycopyrronium bromide + indacaterol maleate (Ultibro), prednisone and salbutamol (Ventolin).

On 20th December 2017, the patient started mepolizumab (subcutaneous) 100 mg (see dose text). On an unknown date, the patient started Covid Vaccine at an unknown dose and frequency. On an unknown date, an unknown time after starting mepolizumab, the patient experienced death (serious criteria death and GSK medically significant), difficulty breathing (serious criteria hospitalization), blackout (serious criteria hospitalization and GSK medically significant) and low blood pressure. On an unknown date, the outcome of the death was fatal and the outcome of the difficulty breathing was not recovered/not resolved and the outcome of the blackout and low blood pressure were unknown. The reported cause of death was unknown cause of death.

It was unknown if the reporter considered the death, difficulty breathing, blackout and low blood pressure to be related to mepolizumab.

Linked case(s) involving the same patient: CA2018GSK103293, CA2018GSK168694, CA2018GSK199352, CA2019AMR147526, CA2019GSK021927, CA2019GSK070985, CA2020AMR004679, CA2020AMR088012, CA2020AMR208962, CA2021262204, CA2021AMR096384, CA2022118479

GSK Receipt Date: [redacted] 2022
Reporter's Comments: This report was submitted by site [redacted] Nucala Patient Support Program (Vista). On [redacted] 2022 it was notified by patient's son that patient was admitted to the hospital on day before reporting [redacted] 2022 due to her breathing and would be staying there for a few days. There was no patient history. Mepolizumab drug used by patient was Nucala. No further information was provided.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporters comments: Patient was admitted to hospital twice on the week of [redacted] 2022 and the week of [redacted] 2022. for blocking out. Patient doesn't remember that exact date of when she was admitted. Also patient received her fourth covid shot on [redacted] 2022. Patient blood pressure was low(96/63) and nurse advised to stay hydrated and take a seat if dizziness occurred. No further information was provided.

Follow-up information received on 26-Sep-2022. This follow-up was considered significant.
Reporter's Comments: Patient's son reached out and advised that his mother (the patient) had passed away. It was unknown if the reporter considered the death, difficulty breathing, blackout and low blood pressure to be related to Covid Vaccine.
Summary of Changes: event death added, concomitant product information updated, narrative updated.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Death, Dyspnoea and loss of consciousness are an unlisted event which are considered unrelated to GSK drug Mepolizumab.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood pressure decreased	96/63	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
unknown			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Unknown cause of death		
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)	

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

no other condition

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1) Mepolizumab Patient Support Program		Project No	
Sponsor Study no. (A.2.3.2) Mepolizumab PSP		Observed study type (A.2.3.3) Other studies	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05758175 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220929 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-607754(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Published		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220712 CCYYMMDD	20220712 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Literature Reference

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2022-607754

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2022-607754

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			76 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021 CCYY		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	SARS-CoV-2 infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	SARS-CoV-2 infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	SARS-CoV-2 infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	SARS-CoV-2 infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Not Related

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021 CCYY	2021 CCYY	0

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SARS-COV-2 INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	SARS-CoV-2 infection
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	COVID-19

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
	3 Months	Unknown

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Summary (B.5)

Case narrative (B.5.1)

This literature-non-study case was reported in a literature article and describes the occurrence of DEATH (Death) and COVID-19 (SARS-CoV-2 infection) in a 76-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 prophylaxis.

LITERATURE REFERENCE:
[redacted]

Concurrent medical conditions included HIV infection and Immunocompromised.

In 2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form.
On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion hospitalization). The patient died in 2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, COVID-19 (SARS-CoV-2 infection) outcome was unknown.

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):
In [redacted] 2021, SARS-CoV-2 test: Positive SARS-CoV-2 on nasopharyngeal swab.
On an unknown date, CD4 lymphocytes: 110 cells per cubic millimetre.
On an unknown date, SARS-CoV-2 antibody test: Negative.
On an unknown date, Viral test: On nasopharyngeal swab collected on post-diagnosis day 68 revealed the presence of infectious virus and On nasopharyngeal swab collected on post-diagnosis day 142 revealed the presence of infectious virus.
On an unknown date, Whole-genome sequencing: Confirmed persistent infection with the same virus.

For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter considered DEATH (Death) and COVID-19 (SARS-CoV-2 infection) to be not related.

The asymptomatic patient was hospitalized for monitoring because of a history of significant immunocompromised related to untreated HIV infection.

Patient had received the second dose 3 months before infection. Patient remained well throughout admission without receiving COVID-19 directed therapies, however patient continued to have detectable SARS-CoV-2 RNA from upper respiratory tract samples until the time of his death from unrelated causes 142 days after the initial diagnosis. The cycle threshold (Ct) values remained below 20.

In [redacted] 2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion hospitalization).

No concomitant and treatment medications were reported.
Company comment: This is a fatal literature non-study case, concerning a 76-year-old man in long term care facility (LTC), with a history of significant immunocompromise related to untreated HIV infection, who was hospitalized with persistent asymptomatic COVID 19 infection and died of unrelated causes 3 months after receiving the second dose of mRNA-1273 vaccine. Relevant history included the first dose of mRNA-1273 and a CD4 count of 110 cells/mm3. No COVID 19 directed therapies were administered throughout 142 days hospitalization. Detectable SARS-CoV-2 RNA was found by nasopharyngeal swabs at days 68 and 142 and by whole genome sequencing because cycle threshold counts remained below 20, which can be associated with prolonged COVID-19 infection. Patient died on 142nd day from unrelated COVID 19 causes. Untreated HIV with low counts and residence in LTC predisposed to susceptibility to COVID, and immunocompromised status predisposed to persistent infections, e.g. COVID, and death as well as less protection/effectiveness of COVID 19 vaccination. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Most recent FOLLOW-UP information incorporated above includes:
On 12-Jul-2022: Upon review on 22-Sep-22 significant corrections were performed. Event causality changed from related to not related and company comment was updated.
On 14-Jul-2022: Follow-up received by safety on 14-Jul-2022 has email with full text article and contains significant information: Reporter information and literature information were updated.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This is a fatal literature non-study case, concerning a 76-year-old man in long term care facility (LTC), with a history of significant immunocompromise related to untreated HIV infection, who was hospitalized with persistent asymptomatic COVID 19 infection and died of unrelated causes 3 months after receiving the second dose of mRNA-1273 vaccine. Relevant history included the first dose of mRNA-1273 and a CD4 count of 110 cells/mm3. No COVID 19 directed therapies were administered throughout 142 days hospitalization. Detectable SARS-CoV-2 RNA was found by nasopharyngeal swabs at days 68 and 142 and by whole genome sequencing because cycle threshold counts remained below 20, which can be associated with prolonged COVID-19 infection. Patient died on 142nd day from unrelated COVID 19 causes. Untreated HIV with low counts and residence in LTC predisposed to susceptibility to COVID, and immunocompromised status predisposed to persistent infections, e.g. COVID, and death as well as less protection/effectiveness of COVID 19 vaccination. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMM	SARS-CoV-2 RT-PCR test		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	CD4 lymphocytes		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	SARS-CoV-2 serology test		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Virus culture		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Whole-genome sequencing		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes

Results of tests and procedures (B.3.2)

CD4 lymphocytes;;;110 cells per cubic millimetre;SARS-CoV-2 antibody test;;;Negative;SARS-CoV-2 test;[redacted]2021;;Positive SARS-CoV-2 on nasopharyngeal swab;Viral test;;;On nasopharyngeal swab collected on post-diagnosis day 68 revealed the presence of infectious virus;Viral test;;;On nasopharyngeal swab collected on post-diagnosis day 142 revealed the presence of infectious virus;Whole-genome sequencing;;;Confirmed persistent infection with the same virus

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	HIV infection	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Immunocompromised	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05758175 (1)	Page#7

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e) Ontario	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Canada Vigilance AER#:	E2B_05758175 (1)	Page#8

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
[redacted]	CANADA	[redacted]		1925	95 Years	Male	Unk	[redacted]		2021

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Passed away [Death]
Difficulty breathing [Breathing difficult]

Case Description: This solicited report from Canada was received by Sanofi (Mfr. no. 2021SA057379) on [redacted] 2021 from a consumer (daughter of the patient) via PSP_LEUPROLIDE[redacted] and was sent to Tolmar on [redacted] 2021 regarding a 95 year-old elderly male patient (Patient ID [redacted] who experienced difficulty breathing (Dyspnea) during Eligard (Leuprolide acetate) 22.5 mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED Date: 18-FEB-2021
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- [ ] INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [ ] OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 22.5 mg {Lot # 11396A;11395A;UNK}
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous (Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 22.5 mg, q 3 month	#1) Subcutaneous
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Prostate cancer (Prostate cancer)
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 24-NOV-2020 / Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Prostate cancer (Prostate cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Tolmar, Inc.
[redacted] PharmD
701 Centre Ave
Fort Collins, CO 80526 UNITED STATES

26. REMARKS

24b. MFR CONTROL NO.
21CA025579

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
[redacted] 2021

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Study

DATE OF THIS REPORT
[redacted] 2021

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

[redacted] 2021 11:41

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ADDITIONAL INFORMATION

ATIA - 19(1)

7+13. DESCRIBE REACTION(S) continued

The patient's medical history was not reported. Current condition included prostate cancer.

Concomitant medications were not provided.

The patient began receiving Eligard 22.5 mg, every 3 months, subcutaneously, since 11 Dec 2018 (Lot number and Expiration date not reported). The patient received his most recent dose of Eligard 22.5 mg, every 3 months, subcutaneously, on 24 Nov 2020 (Lot number and Expiration date carton: not reported; Lot number Syringe A: 11396A; Expiration date: Apr 2022; Lot number Syringe B: 11395A; Expiration date: Mar 2022).

On [redacted] 2021, the patient received his second Covid-19 vaccine. Since then, the patient had been placed on nasal prongs with difficulty breathing. The reporter would call the oncologist before scheduling patient's next injection which was due on [redacted] 2021. The action taken with the suspect product was dose not changed. De-challenge and re-challenge were not applicable. The outcome of the event was unknown.

The reporter did not assess the seriousness and causality of the event regarding Eligard therapy.

On [redacted] 2021, follow-up information was received by Sanofi (Mfr. no. 2021SA057379) from a consumer (daughter of the patient) via PSP_LEUPROLIDE_[redacted] and was sent to Tolmar on [redacted] 2021. Added event of passed away (Death). Updated action taken.

On [redacted] 2021, 2 years, 2 months and 8 days after starting Eligard therapy, the patient passed away due to an unknown cause. The patient was 95 years-old at the time of his death. It was unknown if an autopsy was performed. The action taken with the suspect product, de-challenge and re-challenge were not applicable. The outcome of the event was fatal.

The reporter assessed the event as serious (Death) and did not assess the causality of the event regarding Eligard therapy.

No further information was provided.

Evaluator Comment (Tolmar): This 95 year old male experienced dyspnea and died while on Eligard therapy for prostate cancer. Tolmar assessed the event of death as serious due to fatal outcome, dyspnea was assessed as not serious event as no patient jeopardy was reported. Tolmar assessed the causal role of Eligard (drug component) in the event of death as not assessable as lack of information regarding cause of death, autopsy details, events or circumstances preceding death, clinical state of underlying prostate cancer, relevant medical history, concomitant medications and supportive investigations done precludes meaningful medical assessment of the report. However, based on the available information, advanced age underlying prostate cancer are pre-existing risk factors for the reported event. Dyspnea is also assessed as not related to Eligard components as the event occurred following the COVID-19 vaccine, indicative of a potential reaction to the vaccine.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 22.5 mg; Regimen #2	22.5 mg, q 3 month; Subcutaneous	Prostate cancer (Prostate cancer)	11-DEC-2018 / Unknown; Unknown
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous injection {Lot # 11396A;11395A;UNK}; Regimen #1	; Unknown	Unknown	Unknown; Unknown

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ATIA - 19(1)

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH (Day / Month / Year)	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET (Day / Month / Year)
[redacted]	CANADA	[redacted] / 1925	95 Years	Male	Unk	[redacted] / 2021

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Passed away due to congestive heart failure [Congestive heart failure]
Difficulty breathing [Breathing difficult]

Case Description: This solicited report from Canada was received by Sanofi (Mfr. no. 2021SA057379) on [redacted] 2021 from a consumer (daughter of the patient) via PSP_LEUPROLIDE_[redacted] and was sent to Tolmar on [redacted] 2021 regarding a 95 year-old elderly male patient (Patient ID [redacted] who experienced difficulty breathing (Dyspnea) during Eligard (Leuprolide acetate) 22.5 mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED Date: 18-FEB-2021
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- [ ] INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [ ] OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 22.5 mg {Lot # 11396A; 11395A; UNK}
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous (Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 22.5 mg, q 3 month	#1) Subcutaneous
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Prostate cancer (Prostate cancer)
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 24-NOV-2020 / Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Prostate cancer (Prostate cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Tolmar, Inc.
[redacted] PharmD
701 Centre Ave
Fort Collins, CO 80526 UNITED STATES

26. REMARKS

24b. MFR CONTROL NO.
21CA025579

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
19-MAR-2021

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Study

DATE OF THIS REPORT
25-MAR-2021

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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ADDITIONAL INFORMATION

ATIA - 19(1)

7+13. DESCRIBE REACTION(S) continued

The patient's medical history was not reported. Current condition included prostate cancer.

Concomitant medications were not provided.

The patient began receiving Eligard 22.5 mg, every 3 months, subcutaneously, since 11 Dec 2018 (Lot number and Expiration date not reported). The patient received his most recent dose of Eligard 22.5 mg, every 3 months, subcutaneously, on 24 Nov 2020 (Lot number and Expiration date carton: not reported; Lot number Syringe A: 11396A; Expiration date: Apr 2022; Lot number Syringe B: 11395A; Expiration date: Mar 2022).

On [redacted] 2021, the patient received his second Covid-19 vaccine. Since then, the patient had been placed on nasal prongs with difficulty breathing. The reporter would call the oncologist before scheduling patient's next injection which was due on [redacted] 2021. The action taken with the suspect product was dose not changed. De-challenge and re-challenge were not applicable. The outcome of the event was unknown.

The reporter did not assess the seriousness and causality of the event regarding Eligard therapy.

On [redacted] 2021, follow-up information was received by Sanofi (Mfr. no. 2021SA057379) from a consumer (daughter of the patient) via PSP_LEUPROLIDE_[redacted] and was sent to Tolmar on [redacted] 2021. Added event of passed away (Death). Updated action taken.

On [redacted] 2021, 2 years, 2 months and 8 days after starting Eligard therapy, the patient passed away due to an unknown cause. The patient was 95 years-old at the time of his death. It was unknown if an autopsy was performed. The action taken with the suspect product, de-challenge and re-challenge were not applicable. The outcome of the event was fatal.

The reporter assessed the event as serious (Death) and did not assess the causality of the event regarding Eligard therapy.

No further information was provided.

On 19 Mar 2021, follow-up information was received by Sanofi (Mfr. no.: 2021SA057379) from a consumer (patient's daughter in law) and was sent to Tolmar on 22 Mar 2021. Added new reporter (daughter in law) and cause of death. Updated verbatim and coding of the event from "Passed away (Death)" to "Passed away due to congestive heart failure (Congestive heart failure)". Upon internal review, COVID-19 vaccine was added as co-suspect. This report no longer meets expedited reporting criteria therefore the case is been downgraded.

Co-suspect product included COVID-19 vaccine for COVID-19 prophylaxis.

On [redacted] 2021, 2 years, 2 months and 8 days after starting Eligard therapy, the patient passed away due to congestive heart failure. It was unknown if an autopsy was performed. Moreover, reporter was not able to provide which COVID vaccine the patient received. She was not aware if the patient's death was reported to Health Canada and gave consent for both her contact and doctor's contact information to be shared. The outcome of the event was fatal.

The reporter assessed the event as serious (Death) and did not assess the causality of the event regarding Eligard therapy.

Evaluator Comment (Tolmar): This 95-year-old male patient passed away due to congestive heart failure while on Eligard therapy for prostate cancer. Before his death, he also experienced dyspnea. COVID-19 vaccine is considered co-suspect. Tolmar assessed congestive heart failure as serious due to fatal outcome (death); dyspnea is assessed as non-serious (no patient jeopardy was reported). The causal role of Eligard (drug and device component) for the events is assessed as not related. Given the known pathology and risk factors for congestive heart failure and the drug's safety profile, a causal association between the event and Eligard is considered unlikely. The advanced age of the patient is a risk factor. Dyspnea occurred following the COVID-19 vaccine, indicative of a potential reaction to the vaccine. Likely concurrent congestive heart failure is another plausible explanation for dyspnea.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 22.5 mg; Regimen #2	22.5 mg, q 3 month; Subcutaneous	Prostate cancer (Prostate cancer)	11-DEC-2018 / Unknown; Unknown

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Mfr. Control Number: 21CA025579

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous injection {Lot # 11396A; 11395A; UNK}; Regimen #1	; Unknown	Unknown	Unknown; Unknown
#3) COVID-19 VACCINE (COVID-19 VACCINE) ; Regimen #1	UNK; Unknown	COVID-19 prophylaxis (COVID-19 prophylaxis)	Unknown; Unknown

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: [redacted]@sanofi.com>
Sent: 2021-04-23 9:37 AM
To: Seguin, Michelle (HC/SC); Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Cc: [redacted] Canada Pharmacovigilance /CA
Subject: RE: Health Canada Follow-Up Clarification Request_2021SA057379 (Tolmar 21CA025579)

Categories: Michelle

Good morning Ms. Séguin,

In an effort to gather additional information and answers to your questions below, Sanofi has actively sought follow-up information with the Healthcare professional involved in the care of this patient.
To date, no additional information has been received by Sanofi relative to this report. Shall further information become available, Sanofi will ensure that this is submitted to Health Canada via the standard expediting reporting procedure.

Thank you,
Kind regards,

[redacted]
Country Safety Head (CSH) Back-up / Project Leader, Pharmacovigilance
(T) [redacted] (F) [redacted] (M) [redacted] [redacted]@sanofi.com
SANOFI CANADA – 2905, Pl. Louis-R.-Renaud – Laval (QC) – Canada – H7V 0A3
SANOFI
www.sanofi.ca

From: Seguin, Michelle (HC/SC) <michelle.seguin@canada.ca> **On Behalf Of** Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: Friday, April 9, 2021 4:17 PM
To: [redacted]@sanofi.com>; Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca>
Cc: Canada Pharmacovigilance /CA <canada.pharmacovigilance@sanofi.com> [redacted]@sanofi.com>
Subject: RE: Health Canada Follow-Up Clarification Request

Good afternoon [redacted]

Re: Health Canada Follow-Up Clarification Request

As a result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified individual case safety reports (ICSRs) where clarification is needed. Please investigate, clarify and resubmit case information for the following ICSRs that require clarification or have discrepancies which may impact case evaluation and/or signal detection:

MAH Case Number	Canada Vigilance Case Number	Clarification Requested

Page: 913 of/de 2,140
A2023000085

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ATIA - 19(1)

Safety report ID: 21CA025579 reported to HC on behalf of Tolmar, Fort Collins, USA concerning suspect drugs: **ELIGARD** (Sanofi-Aventis Canada Inc.) and co-suspect: "**COVID-19 vaccine**" (unspecified MAH) and stating the following in the case narrative: - On [redacted]2021, follow-up information was received by Sanofi (Mfr. no. 2021SA057379) from a consumer (daughter of the patient) via PSP_LEUPROLIDE[redacted] and was sent to Tolmar on [redacted]2021 - FU Information was received by Sanofi (Mfr. no.: 2021SA057379) from a consumer (patient's daughter in law) and was sent to Tolmar on 22 Mar 2021 Received by Health Canada on: 24/02/2021	000940311(1)	Specifically, our evaluators wish to request the following information: • Please provide any information regarding the time to onset after vaccination. • Please provide any information regarding clinical status before the vaccination. Specifically, any concomitant medications. • Please provide any information regarding more detailed information about the event of congestive heart failure, including any treatment. • Please provide any information regarding medical confirmation of the cause of death, and autopsy report.

Please provide a response within 15 days upon receipt of this correspondence, April 9th , 2021, in order to allow for sufficient time for case evaluation. Kindly send response to our generic Canada Vigilance COVID-19 Vaccine account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca) with a cc to myself, Michelle Séguin: michelle.seguin@canada.ca.

If you require further information within the scope of this request, please do not hesitate to contact me.

Thank you in advance for your much appreciated collaboration.

Sincerely,

Michelle Séguin on behalf of:
The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

"

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A2023000085

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: [redacted]@sanofi.com>
Sent: 2021-04-23 9:37 AM
To: Seguin, Michelle (HC/SC); Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Cc: [redacted]anada Pharmacovigilance /CA
Subject: RE: Health Canada Follow-Up Clarification Request_2021SA057379 (Tolmar 21CA025579)

Categories: Michelle

Good morning Ms. Séguin,

In an effort to gather additional information and answers to your questions below, Sanofi has actively sought follow-up information with the Healthcare professional involved in the care of this patient.
To date, no additional information has been received by Sanofi relative to this report. Shall further information become available, Sanofi will ensure that this is submitted to Health Canada via the standard expediting reporting procedure.

Thank you,
Kind regards,

[redacted]
Country Safety Head (CSH) Back-up / Project Leader, Pharmacovigilance
(T) [redacted] (F) [redacted] (M) [redacted] [redacted]
SANOFI CANADA – 2905, Pl. Louis-R.-Renaud – Laval (QC) – Canada – H7V 0A3
SANOFI
www.sanofi.ca

From: Seguin, Michelle (HC/SC) <michelle.seguin@canada.ca> **On Behalf Of** Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: Friday, April 9, 2021 4:17 PM
To: [redacted]@sanofi.com>; Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca>
Cc: Canada Pharmacovigilance /CA <canada.pharmacovigilance@sanofi.com> [redacted]@sanofi.com>
Subject: RE: Health Canada Follow-Up Clarification Request

Good afternoon Catherine,

Re: Health Canada Follow-Up Clarification Request

As a result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified individual case safety reports (ICSRs) where clarification is needed. Please investigate, clarify and resubmit case information for the following ICSRs that require clarification or have discrepancies which may impact case evaluation and/or signal detection:

MAH Case Number	Canada Vigilance Case Number	Clarification Requested

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ATIA - 19(1) **Safety report ID:** 21CA025579 reported to HC on behalf of Tolmar, Fort Collins, USA concerning suspect drugs: **ELIGARD** (Sanofi-Aventis Canada Inc.) and co-suspect: "**COVID-19 vaccine**" (unspecified MAH) and stating the following in the case narrative: - On [redacted] 2021, follow-up information was received by Sanofi (Mfr. no. 2021SA057379) from a consumer (daughter of the patient) via PSP_LEUPROLIDE_[redacted] and was sent to Tolmar on [redacted] 2021 - FU Information was received by Sanofi (Mfr. no.: 2021SA057379) from a consumer (patient's daughter in law) and was sent to Tolmar on 22 Mar 2021 Received by Health Canada on: 24/02/2021	000940311(1)	Specifically, our evaluators wish to request the following information: • Please provide any information regarding the time to onset after vaccination. • Please provide any information regarding clinical status before the vaccination. Specifically, any concomitant medications. • Please provide any information regarding more detailed information about the event of congestive heart failure, including any treatment. • Please provide any information regarding medical confirmation of the cause of death, and autopsy report.

Please provide a response within 15 days upon receipt of this correspondence, April 9th , 2021, in order to allow for sufficient time for case evaluation. Kindly send response to our generic Canada Vigilance COVID-19 Vaccine account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca) with a cc to myself, Michelle Séguin: michelle.seguin@canada.ca.

If you require further information within the scope of this request, please do not hesitate to contact me.

Thank you in advance for your much appreciated collaboration.

Sincerely,

Michelle Séguin on behalf of:
The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

"

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ATIA - 19(1)

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH (Day / Month / Year)	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET (Day / Month / Year)
[redacted]	CANADA	[redacted] / 1925	95 Years	Male	Unk	[redacted] / 2021

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Passed away due to congestive heart failure [Congestive heart failure]
Passed away due to natural prostate cancer [Progression of prostate cancer]
Difficulty breathing [Breathing difficult]

Case Description: This solicited report from Canada was received by Sanofi (Mfr. no.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED Date: 18-FEB-2021
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- [ ] INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [ ] OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 22.5 mg {Lot # 11396A; 11395A; UNK}
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous (Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 22.5 mg, q 3 month	#1) Subcutaneous
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Prostate cancer (Prostate cancer)
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 24-NOV-2020 / Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Prostate cancer (Prostate cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Tolmar, Inc.
[redacted] PharmD
701 Centre Ave
Fort Collins, CO 80526 UNITED STATES

26. REMARKS

24b. MFR CONTROL NO.
21CA025579

24c. DATE RECEIVED BY MANUFACTURER
23-APR-2021

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☒ HEALTH PROFESSIONAL ☒ OTHER: Study

DATE OF THIS REPORT
27-APR-2021

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

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ADDITIONAL INFORMATION

ATIA - 19(1)

7+13. DESCRIBE REACTION(S) continued

2021SA057379) on [redacted] 2021 from a consumer (daughter of the patient) via PSP_LEUPROLIDE [redacted] and was sent to Tolmar on [redacted] 2021 regarding a 95 year-old elderly male patient (Patient ID: [redacted] who experienced difficulty breathing (Dyspnea) during Eligard (Leuprolide acetate) 22.5 mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report.

The patient's medical history was not reported. Current condition included prostate cancer.

Concomitant medications were not provided.

The patient began receiving Eligard 22.5 mg, every 3 months, subcutaneously, since 11 Dec 2018 (Lot number and Expiration date not reported). The patient received his most recent dose of Eligard 22.5 mg, every 3 months, subcutaneously, on 24 Nov 2020 (Lot number and Expiration date carton: not reported; Lot number Syringe A: 11396A; Expiration date: Apr 2022; Lot number Syringe B: 11395A; Expiration date: Mar 2022).

On [redacted] 2021, the patient received his second Covid-19 vaccine. Since then, the patient had been placed on nasal prongs with difficulty breathing. The reporter would call the oncologist before scheduling patient's next injection which was due on [redacted] 2021. The action taken with the suspect product was dose not changed. De-challenge and re-challenge were not applicable. The outcome of the event was unknown.

The reporter did not assess the seriousness and causality of the event regarding Eligard therapy.

On [redacted] 2021, follow-up information was received by Sanofi (Mfr. no. 2021SA057379) from a consumer (daughter of the patient) via PSP_LEUPROLIDE_[redacted] and was sent to Tolmar on [redacted] 2021. Added event of passed away (Death). Updated action taken.

On [redacted] 2021, 2 years, 2 months and 8 days after starting Eligard therapy, the patient passed away due to an unknown cause. The patient was 95 years-old at the time of his death. It was unknown if an autopsy was performed. The action taken with the suspect product, de-challenge and re-challenge were not applicable. The outcome of the event was fatal.

The reporter assessed the event as serious (Death) and did not assess the causality of the event regarding Eligard therapy.

No further information was provided.

On 19 Mar 2021, follow-up information was received by Sanofi (Mfr. no.: 2021SA057379) from a consumer (patient's daughter in law) and was sent to Tolmar on 22 Mar 2021. Added new reporter (daughter in law) and cause of death. Updated verbatim and coding of the event from "Passed away (Death)" to "Passed away due to congestive heart failure (Congestive heart failure)". Upon internal review, COVID-19 vaccine was added as co-suspect. This report no longer meets expedited reporting criteria therefore the case is been downgraded.

Co-suspect product included COVID-19 vaccine for COVID-19 prophylaxis.

On [redacted] 2021, 2 years, 2 months and 8 days after starting Eligard therapy, the patient passed away due to congestive heart failure. It was unknown if an autopsy was performed. Moreover, reporter was not able to provide which COVID vaccine the patient received. She was not aware if the patient's death was reported to Health Canada and gave consent for both her contact and doctor's contact information to be shared. The outcome of the event was fatal.

The reporter assessed the event as serious (Death) and did not assess the causality of the event regarding Eligard therapy.

On 23 Apr 2021, follow up information was received by Sanofi (Mfr. No.: 2021SA057379) and sent to Tolmar on 26 Apr 2021. Added new healthcare professional (HCP) reporter, update medically confirm to yes, added new cause of death, added new event of "Passed away due to natural prostate cancer (Progression of prostate cancer)", updated causality, and updated narrative.

The patient was under the care of a doctor in nursing home at the time of the breathing difficulty following the second dose of COVID-19 vaccine administration; therefore the reporting HCP did not know the onset date of the breathing difficulty. It was unknown if use of other medications or other pre-existing conditions/risk factors caused the breathing difficulty. The patient was not hospitalized prior to his death. The HCP mentioned the patient died due to natural prostate cancer progression (conflicting information previously reported as congestive heart failure). It was unknown if an autopsy was performed. The patient did not know if investigational tests were performed confirming the congestive heart failure (previously reported as cause of the death). It was unknown if the cause of death was caused by the use of other medications. The action taken with the suspect product, de-challenge and re-challenge were not applicable. The outcome of the new event of passed away due to natural prostate cancer was fatal.

The HCP assessed the new event of passed away due to natural prostate cancer as serious (Death) and assessed causality of difficulty breathing and death due to natural prostate cancer progression as not related to Eligard treatment.

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ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Evaluator Comment (Tolmar): This 95-year-old male patient passed away due to congestive heart failure and natural prostate cancer (Progression of prostate cancer) while on Eligard therapy for prostate cancer. Before his death, he also experienced dyspnea. COVID-19 vaccine is considered co-suspect. Tolmar assessed congestive heart failure and progression of prostate cancer as serious due to fatal outcome (death); dyspnea is assessed as non-serious (no patient jeopardy was reported). The causal role of Eligard (drug and device component) for the events is assessed as not related. Given the known pathology and risk factors for congestive heart failure and the drug's safety profile, a causal association between the event and Eligard is considered unlikely. The advanced age of the patient is a risk factor. The underlying prostate cancer (and its nature to progress) in this elderly patient can likely explain the event. Dyspnea occurred following the COVID-19 vaccine, indicative of a potential reaction to the vaccine. The likely concurrent congestive heart failure is another plausible explanation for dyspnea.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 22.5 mg; Regimen #2	22.5 mg, q 3 month; Subcutaneous	Prostate cancer (Prostate cancer)	11-DEC-2018 / Unknown; Unknown
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous injection {Lot # 11396A; 11395A; UNK}; Regimen #1	; Unknown	Unknown	Unknown; Unknown
#3) COVID-19 VACCINE (COVID-19 VACCINE) ; Regimen #1	UNK; Unknown	COVID-19 prophylaxis (COVID-19 prophylaxis)	Unknown; Unknown

ATIA - 19(1)
HC-SC REC'D 20-AU-2021

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Reference number	[redacted]
Date Reported	2021-08-16
Facility ID#	[redacted]
Facility	
Exact location	
Date the problem was discovered	2021-[redacted]
Description of the problem	A 86 year old female was brought to the [redacted] via EMS with headache and neck tightness radiating into her shoulders. She had recently received her 2nd dose of Pfizer vaccination 1 day prior. She was downloaded to the waiting room (WR). She was found by a volunteer in the WR unresponsive with a GCS=3. The patient was intubated and a CT head demonstrated a subarachnoid hemorrhage. The patient was taking apixaban. The ED physician reviewed the case with neurosurgery, however, no intervention could be offered. The patient was extubated and made palliative (C2 goal of care). The Hospitalist Service consulted for admission. The patient was admitted to the unit and passed away on [redacted] 2021.
What was the outcome for the patient at the time of the problem	subarachnoid hemorrhage
Reason for seriousness	died on [redacted] 2021
After the problem occurred what interventions were implemented	
Was the adverse drug reaction serious	yes
SADR When did the patient start taking the medication or other substance	chronic therapy
SADR If applicable when did the patient stop taking the	2021-[redacted]

ATIA - 19(1)

HC-SC REC'D 20-AU-2021

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medication or other substance	
SADR If applicable when did the patients health restore to its state prior to the adverse drug reaction If health was not restored to baseline at the time of the report then answer N/A with one of the following comments: • recovering • not recovered • recovered with sequelae • died • unknown	N/A, died
SADR If known what was the result of the adverse drug reaction on the patients health	died
SADR What relevant medical conditions directly related to the adverse drug reaction	
SADR What other medications or substances was the patient taking at the time of the adverse drug reaction	Pfizer brand Covid-19 vaccine (received second dosage on [redacted] 2021)
SADR If known what is the Drug	

ATIA - 19(1)
HC-SC REC'D 20-AU-2021

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Identification Number DIN	
Med What was the name of the correct medication or substance involved	apixaban
Date of birth	86 years old
Sex	female
Organization contact	[redacted]
Phone number	
Email	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05857713 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220824 CCYYMMDD	
	HC Initial Received Date: 20220824 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A294046()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220822 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220822 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2022A294046

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) HEALTH CANADA MC Canada AER Number AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B 05453849 [redacted] 202200538891 CA-AstraZeneca-2022A294046

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 69 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cholelithiasis
26.0	Crohn's disease
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
520 Milligram		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Crohn's disease
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHOLELITHIASIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cholelithiasis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cholelithiasis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CROHN'S DISEASE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Crohn's disease		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Crohn's disease		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer via regulatory authority in Canada (HEALTH CANADA), concerning a female patient of unknown ethnic origin (age 69 years).

No medical history was reported and no concomitant products were reported.

On an unknown date, the patient received Covid-19 Vaccine (covid-19 vaccine nrvv ad (chadox1 ncov-19)) total, via intramuscular route, for covid-19 immunisation.

On an unknown date, the patient started treatment with Stelara (ustekinumab) 520 mg, intravenous (not otherwise specified), for crohn's disease.

On an unknown date, the patient experienced cholelithiasis (preferred term: Cholelithiasis), crohn's disease (preferred term: Crohn's disease), died (preferred term: Death)

It was unknown if any action was taken with Covid-19 Vaccine and Stelara.

On an unspecified date, the patient died.

It was not known whether an autopsy was performed. The cause of death was cholelithiasis, crohn's disease and death.

The reporter assessed the events of cholelithiasis, crohn's disease and death to be serious due to seriousness criteria death and important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.CAUSE OF DEATH: CHOLELITHIASIS CAUSE OF DEATH: CROHN'S DISEASE CAUSE OF DEATH: DEATH
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal events of Death, Crohn's disease and Cholelithiasis are not listed in the company core data sheet of AZD1222. Vaccinee age of 69 years could be a risk factor for the event Cholelithiasis, The cause of death is reported as cholelithiasis, crohn's disease and death. Vaccinee's past and current medical history of Crohn's disease could be considered as risk factor for the event Crohn's disease. Due to limited information on circumstances leading to the events, clinical course, other risk factors, Autopsy details, detailed diagnostic and etiologic workup (complete blood count, autoimmune work up, infectious work up, imaging studies), the evaluation did not find evidence to suggest a causal relationship between the fatal events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cholelithiasis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Crohn's disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Death

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05857713 (0)	Page#7

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	HEALTH CANADA

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05867983 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220829 CCYYMMDD
	HC Initial Received Date:	20220829 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-632618(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220823 CCYYMMDD	20220823 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2022-632618

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
irms QMODERNAP	CA-irms-MDCA22-01779 CA-MODERNATX, INC.-MOD-2022-632618

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05867983 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Canada Vigilance AER#:	E2B_05867983 (0)	
Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2) elasomeran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 1 Dosage forms		
Dosage text (B.4.k.6) 1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	
Source of assessment (B.4.k.18.2) Non-Health care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Provided
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pain in limb	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pain in limb	
Source of assessment (B.4.k.18.2) Non-Health care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE ENDED UP DYING FROM THE COVID-19 SHOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAD PAIN IN ARM WHICH WENT TO HIS LEGS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pain in limb
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pain in extremity

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of DEATH (he ended up dying from the COVID-19 shot) in a male patient of an unknown age who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 prophylaxis. The occurrence of additional non-serious events is detailed below.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (he ended up dying from the COVID-19 shot) (seriousness criteria death and medically significant) and PAIN IN EXTREMITY (Had pain in arm which went to his legs). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PAIN IN EXTREMITY (Had pain in arm which went to his legs) outcome was unknown.

No concomitant medications were reported.
It was reported that patient was not sure if it was due to the Moderna vaccine.

No treatment medications were reported.

Company comment: This spontaneous case concerns a unspecified age male patient, with no medical history, who experienced unexpected fatal serious (medically significant) event of death (reported as he ended up dying from the COVID-19 shot), which occurred unspecified days after a dose (dose number not specified) of mRNA-1273 vaccine. The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PAIN IN EXTREMITY (Had pain in arm which went to his legs) outcome was unknown. The benefit risk relationship of mRNA-1273 is not affected by this report.

This case was linked to CA-MODERNATX, INC.-MOD-2022-632612, CA-MODERNATX, INC.-MOD-2022-632626, CA-MODERNATX, INC.-MOD-2022-632628 (E2B Linked Report).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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This spontaneous case concerns a unspecified age male patient, with no medical history, who experienced unexpected fatal serious (medically significant) event of death (reported as he ended up dying from the COVID-19 shot), which occurred unspecified days after a dose (dose number not specified) of mRNA-1273 vaccine. The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PAIN IN EXTREMITY (Had pain in arm which went to his legs) outcome was unknown. The benefit risk relationship of mRNA-1273 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
	BC

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05877576 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220831 CCYYMMDD
	HC Initial Received Date:	20220831 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-635836(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220826 CCYYMMDD	20220826 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2022-635836

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
irms QMODERNAP	CA-irms-MDCA22-01808 CA-MODERNATX, INC.-MOD-2022-635836

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Non-Health care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hearing loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hearing loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Loss of vision	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Loss of vision	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Related

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HIS BODY SHUT DOWN/THEY PUT HIM IN A COMA, AND THEN HE DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE LOST HIS HEARING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hearing loss		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Deafness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE RECEIVED THE VACCINE, AND THEN HE LOST HIS SIGHT.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Loss of vision		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Blindness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEATH (his body shut down/They put him in a coma, and then he died), DEAFNESS (he lost his hearing) and BLINDNESS (he received the vaccine, and then he lost his sight.) in a male patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 prophylaxis.

Concurrent medical conditions included Blood pressure (He had blood pressure problems), Diabetes, Coma (gave it to him when he was in a coma. Ended up dying in the coma) and Broken leg (he went in with a broken leg. and he received the vaccine).

On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (his body shut down/They put him in a coma, and then he died) (seriousness criterion death), DEAFNESS (he lost his hearing) (seriousness criterion medically significant) and BLINDNESS (he received the vaccine, and then he lost his sight.) (seriousness criterion medically significant). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, DEAFNESS (he lost his hearing) and BLINDNESS (he received the vaccine, and then he lost his sight.) outcome was unknown.

Concomitant medications were not reported.
No treatment information was provided by the reporter.

As per the reporter , patient never wanted to take the vaccine but it was administered in the hospital when patient was in coma. Patient said reporter that he would never take the vaccine.

It was reported that patient received vaccine and then he lost his sight and then 3 weeks later patient lost his hearing and his body shut down. Patient was put in coma and patient died.

As per the reporter patient blamed it on the vaccine.

Company comment:
This is a spontaneous case concerning a male patient of unknown age with relevant concurrent medical conditions of blood pressure problems, diabetes, and broken leg. The patient has no reported vaccination history. The patient experienced the unexpected serious fatal event of death, and the unexpected serious (medically significant) events of deafness and blindness. The events exact occurrence was unknown but stated that the events occurred after the unknown dose number of mRNA-1273 vaccine administration. Allegedly the events were described as, on unknown date the patient went in with a broken leg. On unknown date, the patient was in coma when he received the unknown dose number of mRNA-1273 vaccine. On unknown date, after receiving the unknown dose number of mRNA-1273 vaccine, the patient lost his sight and then three weeks later, the patient lost his hearing and his body shut down. It was reported that the patient was put to coma and then he died. No further clinical information was available for medical review. It is unknown if autopsy was performed. The cause of death was not reported. The concurrent medical conditions of blood pressure problems, diabetes and broken leg remain confounders for the event death. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This is a spontaneous case concerning a male patient of unknown age with relevant concurrent medical conditions of blood pressure problems, diabetes, and broken leg. The patient has no reported vaccination history. The patient experienced the unexpected serious fatal event of death, and the unexpected serious (medically significant) events of deafness and blindness. The events exact occurrence was unknown but stated that the events occurred after the unknown dose number of mRNA-1273 vaccine administration. Allegedly the events were described as, on unknown date the patient went in with a broken leg. On unknown date, the patient was in coma when he received the unknown dose number of mRNA-1273 vaccine. On unknown date, after receiving the unknown dose number of mRNA-1273 vaccine, the patient lost his sight and then three weeks later, the patient lost his hearing and his body shut down. It was reported that the patient was put to coma and then he died. No further clinical information wass available for medical review. It is unknown if autopsy was performed. The cause of death was not reported. The concurrent medical conditions of blood pressure problems, diabetes and broken leg remain confounders for the event death. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Blood pressure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
He had blood pressure problems		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Coma	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
gave it to him when he was in a coma. Ended up dying in the coma		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Broken leg	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
he went in with a broken leg. and he received the vaccine		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date (B.1.8e)**
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05887823 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220905 CCYYMMDD	
	HC Initial Received Date: 20220905 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A307189()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220902 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220902 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2022A307189

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) MC Canada AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** [redacted] CA-AstraZeneca-2022A307189

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)** 168 Centimeter	**Patient weight (B.1.3)** 74.8 Kilogram
Date of birth (B.1.2.1) 1947[redacted] CCYYMMDD	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05887823 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Stroke

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	MT0055	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20210423 CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

2ND STROKE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Stroke
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer, concerning a male patient of Caucasian ethnic origin born in 1947 (height 66 in, weight 165 lb).

No medical history was reported and no concomitant products were reported.

On 23-Apr-2021, the patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number MT0055), via intramuscular route, for an unknown indication.

On an unknown date, the patient experienced 2nd stroke (preferred term: Cerebrovascular accident).

Action taken with Astrazeneca Covid-19 Vaccine was not applicable.

The patient died from the event of 2nd stroke on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was 2nd stroke.

The reporter assessed the event of 2nd stroke to be serious due to seriousness criterion death and important medical event.CAUSE OF DEATH: 2ND STROKE
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Cerebrovascular accident (reported as 2ND STROKE) is not listed in the company core data sheet of AZD1222.The vaccinee died from the event of 2nd stroke on an unspecified date. It was not known whether an autopsy was performed. The cause of death was reported as 2nd stroke. Advanced age could be considered as confounding factor for the event. Due to limited information on baseline health condition before vaccination, relevant family history, concurrent conditions and concomitant medications, risk factors (atherosclerosis, cardiovascular disorder, smoking, high cholesterol levels), circumstances surrounding the event, clinical course of the event, treatment given, detailed diagnostic and etiologic workup (complete blood analysis including infectious workup, neurological examination, coagulation profile, cardiac profile, imaging studies of heart and brain), autopsy report if any with a confirmed diagnosis and date of death, the evaluation did not find evidence to suggest aa causal relationship between the fatal event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Stroke	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05891219 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220906 CCYYMMDD	
	HC Initial Received Date: 20220906 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A308826()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20220905 CCYYMMDD	20220905 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	**Company number (A.1.10.2)** CA-AstraZeneca-2022A308826

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada MC Canada AER Number AZPROD0000	E2B_05482328 [redacted] 2022A154136 CA-AstraZeneca-2022A308826

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			69 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cholelithiasis
26.0	Crohn's disease
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	STELARA	
Active Substance names (B.4.k.2.2)		
ustekinumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Crohns disease aggravated
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHOLELITHIASIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cholelithiasis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cholelithiasis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CROHN'S DISEASE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Crohn's disease		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Crohn's disease		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from Pharmacist via the regulatory authority in Canada concerning a female patient of Unknown ethnic origin (age 69 years).

No medical history was reported and No concomitant products were reported.

On an unknown date, The patient received Vaxzevria Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for covid-19 prophylaxis.

On an unknown date, The patient started treatment with Stelara (ustekinumab) Dose Unknown for crohn's disease.

On an unknown date, the patient experienced cholelithiasis (preferred term: Cholelithiasis), crohn's disease (preferred term: Crohn's disease), Death (preferred term: Death).

It was unknown if any action was taken with Vaxzevria Vial Contains 10 Doses Of 0.5ml and Stelara.

The patient died (MedDRA PT: Death) on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was cholelithiasis, crohn's disease and death.

Reporter assessed the events cholelithiasis, crohn's disease and death as serious due to seriousness criteria of death and important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.
CAUSE OF DEATH: CHOLELITHIASIS CAUSE OF DEATH: CROHN'S DISEASE CAUSE OF DEATH: DEATH CHOLELITHIASIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CROHN'S DISEASE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DEATH - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal events of Cholelithiasis, Crohn's disease and Death are not listed in the company core data sheet of AZD1222. The vaccine died on an unspecified date. It was not known whether an autopsy was performed. The cause of death was reported as cholelithiasis, crohn's disease and death. Elderly age and the vaccinees relevant medical history of crohn's disease could be considered as contributory risk factors for the event. Due to limited information on baseline health condition before vaccination, relevant family history, concomitant medications, date of vaccine administration, onset date of the events, details and circumstances surrounding the events, clinical course of the events, treatment given, risk factors, treatment provided, detailed etiologic and diagnostic workup (complete blood tests with infectious profile, liver profile, colonoscopy and imaging of abdomen), autopsy report if any with a confirmed diagnosis and date of death, the evaluation did not find evidence to suggest a caausal relationship between the fatal events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cholelithiasis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Crohn's disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	Health Canada

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c): UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2):

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c): UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Pharmacist

Literature reference(s) (A.2.2):

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a):

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l):

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05929037 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220916 CCYYMMDD
	HC Initial Received Date:	20220916 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202201166063(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220915 CCYYMMDD	20220915 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202201166063

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_05587761 20220425043 CA-PFIZER INC-202201166063

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			90 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05929037 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Arterial occlusive disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SIMPONI	
Active Substance names (B.4.k.2.2)		
golimumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
50 Milligram,1 every 1 (Months)		
Dosage text (B.4.k.6)		
50 mg, monthly		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Ankylosing spondylitis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		946 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	AMLODIPINE	
Active Substance names (B.4.k.2.2)		
amlodipine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
5 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
5 mg, 1x/day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ARTERIAL OCCLUSIVE DISEASE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Arterial occlusive disease		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Arterial occlusive disease		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	COVID-19		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	COVID-19		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug ineffective		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug ineffective		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

NON-INTERVENTIONAL POST-MARKETING STUDY - PROTOCOL TITLE NOT AVAILABLE

This is a non-interventional study report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: E2B_05587761 (Health Canada).

A 90-year-old male patient received BNT162b2 (COMIRNATY), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation; golimumab (SIMPONI), (Batch/Lot number: unknown) for 946 days at 50 mg monthly, subcutaneous for ankylosing spondylitis. The patient's relevant medical history was not reported. Concomitant medication(s) included: AMLODIPINE unknown; AMLODIPINE unknown.
The following information was reported: ARTERIAL OCCLUSIVE DISEASE (death, hospitalization), outcome "fatal"; COVID-19 (death, hospitalization), DRUG INEFFECTIVE (death, hospitalization), outcome "fatal" and all described as "COVID-19". The action taken for golimumab was unknown. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

The reporter's assessment of the causal relationship of "arterial occlusive disease" and "covid-19" with the suspect product(s) BNT162b2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

As there is limited information in the case provided, the causal association be-tween the event and the suspect drug cannot be excluded.
The impact of this report on the benefit-risk profile of the Pfizer product and on the conduct of the study is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3) Other studies	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05932186 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220920 CCYYMMDD
	HC Initial Received Date:	20220920 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202201166637(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220915 CCYYMMDD	20220915 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202201166637

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CAEPISS PFIZERINC	V2208236 CA-PFIZER INC-202201166637

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			35 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cardiac discomfort
26.0	Myopericarditis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EW0221	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	202[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cardiac discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05932186 (0)	Page#3
PHARMACEUTICAL COMPANY	Global Introspection	N/A

MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Cardiac discomfort	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myopericarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myopericarditis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MYOPERICARDITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Myopericarditis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myopericarditis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CARDIAC DISCOMFORT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cardiac discomfort		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cardiac discomfort		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
1440 Minutes	1440 Minutes	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from Regulatory Authority. Regulatory number: V2208236 (CAEFISS).

A 35-year-old male patient received BNT162b2 (COMIRNATY), on [redacted]2021 as dose 1, single (Lot number: EW0221) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: MYOPERICARDITIS (death), outcome "fatal"; CARDIAC DISCOMFORT (death), 1440 min after the suspect product(s) administration, outcome "fatal". The patient date of death was [redacted]2022. Reported cause of death: "Cardiac discomfort", "Myopericarditis". It was not reported if an autopsy was performed.

Clinical course: Level of care obtained: None, MedDRA LLT Terms (Diagnosis): (1)Cardiac discomfort. MedDRA LLT Terms (Medical Case Review): Myopericarditis.

No follow-up attempts are possible. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac discomfort	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myopericarditis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)		

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221124 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202201166442(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220915 CCYYMMDD	20221121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202201166442

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
GlaxoSmithKline Health Canada GlaxoSmithKline PFIZERINC	CA-GLAXOSMITHKLINE-CA2022034800 E2B_05499967 CA2022034800 CA-PFIZER INC-202201166442

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_05499967

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			93 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 4 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Productive cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sputum discoloured	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sputum discoloured	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sputum discoloured	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

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MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Sputum discoloured	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated

Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **MEPOLIZUMAB**	
Active Substance names (B.4.k.2.2) mepolizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 100 Milligram		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Subcutaneous	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0 26.0	**Indication (B.4.k.11b)** Eosinophilic asthma Eosinophilic asthma
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B.4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	

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Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ADVAIR	
Active Substance names (B.4.k.2.2) salmeterol xinafoate fluticasone propionate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 2 Dosage forms,2 every 1 (Days)		
Dosage text (B.4.k.6) 2 DF, 2x/day (2 puff(s), bid, 25/250)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) OLODATEROL HYDROCHLORIDE/TIOTROPIUM BROMIDE MONOHYDRATE	
Active Substance names (B.4.k.2.2) tiotropium bromide monohydrate olodaterol hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PREGABALIN	
Active Substance names (B.4.k.2.2)		
pregabalin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
25 Milligram		
Dosage text (B.4.k.6)		
25 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	SPIRIVA [TIOTROPIUM BROMIDE]	
Active Substance names (B.4.k.2.2)		
TIOTROPIUM BROMIDE		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2 Dosage forms,1 every 1 (Days)		
Dosage text (B.4.k.6)		
2 DF, 1x/day (2 puff(s), qd (every day), 2.5 mcg)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VENTOLINE [SALBUTAMOL]	
Active Substance names (B.4.k.2.2)		
SALBUTAMOL		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2 Dosage forms 1 (As required)		
Dosage text (B.4.k.6)		
2 DF, as needed (2 puff(s), Z 100 mcg as needed)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THAT PATIENT IS DECEASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LUNG INFECTION

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Lung infection
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERMITTENT COUGH/INTERMITTENT DRY COUGH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cough
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cough

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRODUCTIVE COUGH WITH WHITE SECRETIONS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Productive cough
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Productive cough

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DARK GREEN MUCUS SINCE PAST WEEK/WHITE SECRETIONS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sputum discoloured
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Sputum discoloured

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CURRENT INJECTION OUTSIDE THE 7-DAY TREATMENT WINDOW/DRUG DOSE ADMINISTRATION INTERVAL TOO LONG

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Inappropriate schedule of product administration
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Inappropriate schedule of product administration

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Summary (B.5)

Case narrative (B.5.1)

MEPOLIZUMAB PATIENT SUPPORT PROGRAM

This is a non-interventional study report received from contactable reporter(s) (Consumer or other non HCP, Pharmacist and Physician) from Regulatory Authority. Regulatory number: E2B_05499967 (Health Canada). Other Case identifier(s): CA2022034800 (GlaxoSmithKline), CA-GLAXOSMITHKLINE-CA2022034800 (GlaxoSmithKline).

A 93-year-old male patient received BNT162b2 (COMIRNATY), as dose 4 (booster), single (Batch/Lot number: unknown), as dose 3 (booster), single (Batch/Lot number: unknown), as dose 2, single (Batch/Lot number: unknown) and as dose 1, single (Batch/Lot number: unknown) for covid-19 immunisation; mepolizumab (MEPOLIZUMAB), first regimen (Batch/Lot number: unknown) at 100 mg, second regimen (Batch/Lot number: unknown) at 100 mg, third regimen (Lot number: BL2S, Expiration Date: 30Jun2023) for 259 days at 100 mg (100 mg (100 mg, z, every 4 weeks)), fourth regimen (Lot number: H36E, Expiration Date: 30Sep2023) and fifth regimen (Lot number: H36E, Expiration Date: 30Sep2023), all subcutaneous for asthma; mepolizumab (MEPOLIZUMAB), (Batch/Lot number: unknown) at 100 mg, subcutaneous for asthma. The patient's relevant medical history was not reported. Concomitant medication(s) included: ADVAIR unknown; INSPIOLTO RESPIMAT unknown; PREGABALIN unknown; SPIRIVA [TIOTROPIUM BROMIDE] unknown; VENTOLINE [SALBUTAMOL].
The following information was reported: DEATH (death, hospitalization, medically significant), outcome "fatal", described as "THAT PATIENT IS DECEASED"; PNEUMONIA (hospitalization, medically significant), outcome "not recovered", described as "LUNG INFECTION"; COUGH (hospitalization, medically significant), outcome "unknown", described as "INTERMITTENT COUGH/INTERMITTENT DRY COUGH"; PRODUCTIVE COUGH (hospitalization, medically significant), outcome "unknown", described as "PRODUCTIVE COUGH WITH WHITE SECRETIONS"; SPUTUM DISCOLOURED (hospitalization, medically significant), outcome "unknown", described as "DARK GREEN MUCUS SINCE PAST WEEK/WHITE SECRETIONS"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (non-serious), outcome "unknown", described as "CURRENT INJECTION OUTSIDE THE 7-DAY TREATMENT WINDOW/Drug dose administration interval too long". The patient underwent the following laboratory tests and procedures: Oxygen saturation: 96 %, notes: Nasal O2 adjusted from 8 LPM to 7.5 LPM. The action taken for mepolizumab and mepolizumab was unknown. Therapeutic measures were taken as a result of pneumonia, cough, productive cough, sputum discoloured. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

The reporter's assessment of the causal relationship of "that patient is deceased", "lung infection", "intermittent cough/intermittent dry cough", "productive cough with white secretions" and "dark green mucus since past week/white secretions" with the suspect product(s) BNT162b2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow up (12Oct2022): This is a follow up non-interventional study report from a new contactable Pharmacist from Regulatory Authority. Regulatory number: E2B_05499967 (Health Canada). This information was initially reported to Health Canada between 26Apr2022 and 16Jun2022 from an unknown Market Authorization Holder and AER # CA2022034800. Updated information included: Added new reporter (pharmacist), new event (death) and new seriousness for the reported events (Death), Outcome of the events (Updated to Fatal) for the events pneumonia, cough, productive cough, sputum discoloured.

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.

Follow-up (21Nov2022): This is a Non-Interventional study report received from the Health Canada Regulatory Authority in response to an Access to Information Request (ATI Request) completed by Pfizer Canada. The regulatory authority report number is E2B_05499967. This information was initially reported to Health Canada on 2022 (Health Canada Latest Received Date: 16Jun2022) from other Market Authorization Holter GlaxoSmithKline. Other MAH Reference Number: CA-GLAXOSMITHKLINE-CA2022034800. This report was also incorrectly submitted to the US FDA with Biologic License Application number 125742 for BNT162B2 and is now being submitted with the correct Emergency Use Authorization number 027034 for BNT162B2. Updated information included: Study name, new reporter, lab data, dose descriptions for suspect, co-suspect details (Mepolizumab), concomitant medications information, events (that patient is deceased and Lung infection) and clinical information in narrative.

This case was reported by a consumer via patient support programs and described the occurrence of unknown cause of death in a 93-year-old male patient who received mepolizumab solution for injection in pre-filled pen (batch number BL2S, expiry date 30Jun2023) for eosinophilic asthma. Co-suspect products included mepolizumab autoinjector device administration system (batch number BL2S, expiry date 30Jun2023) for eosinophilic asthma, mepolizumab solution for injection in pre-filled pen (batch number H36E, expiry date 30Sep2023) for eosinophilic asthma, mepolizumab autoinjector device administration system (batch number H36E, expiry date 30Sep2023) for eosinophilic asthma and tozinameran (Comirnaty) for covid-19 prophylaxis. Additional subject notes included Patient was Afebrile. Patient history was unknown. Concomitant products included fluticasone propionate+ salmeterol xinafoate (Advair), salbutamol (Ventolin), olodaterol hydrochloride + tiotropium bromide (Inspiolto), tiotropium bromide (Spiriva) and pregabalin. On an unspecified date the patient started mepolizumab (subcutaneous) 100 mg, mepolizumab autoinjector device, mepolizumab (subcutaneous) 100 mg and mepolizumab autoinjector device. On an unknown date, the patient started Comirnaty at an unknown dose and frequency. On an unknown date, the dose was changed to an unknown dose and frequency. On an unknown date, the dose was changed to an unknown and frequency. On the dose was changed to an unknown dose and frequency. On 232 days after starting mepolizumab, mepolizumab autoinjector device, mepolizumab and mepolizumab autoinjector device, the patient experienced drug dose administration interval too long. On an unknown date, the patient experienced unknown cause of death (serious criteria death and GSK (GlaxoSmithKline) medically significant), lung infection (serious criteria hospitalization and GSK medically significant), cough, sputum discolored and productive cough. The subject was treated with prednisone and antibiotics NOS (Antibiotic (Active Ingredient Unknown)). On an unknown date, the outcome of the unknown cause of death was fatal and the outcome of the lung infection was not recovered/not resolved and the outcome of the drug dose administration interval too long, cough, sputum, discolored and productive cough were unknown. The reported cause of death was unknown cause of death. It was unknown if the reporter considered the

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unknown cause of death, lung infection, cough, sputum discolored and productive cough to be related to mepolizumab, mepolizumab autoinjector device, mepolizumab and mepolizumab autoinjector device. This report is made by GSK without prejudice and does not imply any admission or liability for the incident or its consequences.

Reporter's Comments: This report was submitted via the online direct entry reporting system. The patient was also the reporter. Reporter type was consumer. Post infusion report mentioned that the patient with intermittent cough but stable. Wife present. Patient said he had dark green mucus since past week and was afebrile. Patient was advised via phone by his physician yesterday to start his action plan. Patient said he would start his Prednisone and antibiotic this afternoon. Injection well tolerated. No issues. Patient stable at writer's departure. No further information provided. Patient history was unknown. Reporter and Health Care Provider (HCP) did not consent to contact.

Follow-up information received on an unspecified date 2022. It was reported that on an unknown date patient experienced productive cough. On an unknown date, outcome of the event productive cough. The causality of the event productive cough was unknown. Reporter's Comments: Post infusion report: Patient stable, wife present. Intermittent dry cough noted. Patient had productive cough with white secretions yesterday evening per wife. Respiratory therapist present. Nasal O2 (oxygen) adjusted from 8 LPM to 7.5 LPM as O2 saturation reading was 96%. Injection tolerated well. No issues. Patient stable at depart. No further information provided.

Follow-up information received on an unspecified date 2022.
Reporter's Comments: Patient's wife reported patient was currently hospitalized since last week. Wife did not provide reason of hospitalization.

Follow-up information received on an unspecified date in 2022.
Reporter's Comments: Post infusion report. Patient hospitalized for lung infection. Patient on prednisone 5 mg. New medicine pregabalin 25 mg. Patient has 4th dose COVID-19 Pfizer vax (vaccine). Patient has appointment with doctor. Injection well tolerated. No issues. Patient stable at departure. Patient missed schedule dose of injection on. Patient's current injection outside the 7-day treatment window. Last dose of drug was administrated on. It was unknown if the reporter considered Lung infection to be relates to COVID-19 vaccine. No further information provided.

Follow-up information received on an unspecified date in 2022.
Reporter's Comments: This case was received via Nucala Patient Support Program (Vista). Mepolizumab dose was given every 4 weeks. Patient's wife reported patient currently hospitalized due to lung infection since past 3 weeks. It was unknown if the reporter considered the lung infection, cough, sputum discolored and productive cough to be related Comirnaty. No further information provided.

Follow-up information received on an unspecified date in 2022.
Reporter's Comments: Patient was moved to palliative approach, Nucala was to be stopped. No further information provided.
Additional supportive information: Mepolizumab drug used by patient was Nucala.

Follow-up information received on an unspecified date in 2022.
Reporter's Comments: Case was received by pharmacist via Nucala Patient Support Program (Vista). It was reported that patient was deceased. No further information provided. It was unknown if autopsy was performed. It was unknown if the reporter considered the unknown cause of death, lung infection, cough, sputum discolored and productive cough to be related to Comirnaty.

Reporter's comments: Not provided.
Sender's comments: Not provided.

Relevant medical history/ Concurrent conditions text noted patient was Afebrile. Patient history was unknown.

No follow-up attempts are possible. No further information is expected

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

As there is limited information in the case provided, the causal association between the reported events and the suspect drug cannot be excluded and are Related to the suspected drug .
Based on known disease pathophysiology, the event of death is assessed as not related to BNT162B2 and more likely due to underlying medical condition.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Oxygen saturation	96	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
%			Yes

Results of tests and procedures (B.3.2)

Oxygen saturation():Nasal O2 adjusted from 8 LPM to 7.5 LPM.

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3) Other studies	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Pharmacist	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3) Other studies	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3) Other studies	

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Canada Vigilance AER#:	E2B_05932303 (2)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05947723 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220926 CCYYMMDD
	HC Initial Received Date:	20220926 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-649414(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220922 CCYYMMDD	20220922 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2022-649414

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2022-649414

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_05947723 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

REPORTER DAD DIED ISOLATED IN LTC AFTER MODERNA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021 CCYY	2021 CCYY	0

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEATH (Reporter dad died isolated in LTC after Moderna) in a male patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 2021 The patient died in 2021. The cause of death was not reported. It is unknown if an autopsy was performed.

Reporter stated that patient was isolated in LTC after moderna vaccine.
No concomitant medication was reported.
No treatment medication was reported.

Company comment:
This fatal spontaneous case concerns a male patient of unknown age, with no medical history reported, who received a dose of mRNA-1273 and died. According to the reporter, the patient died isolated in long term care after receiving moderna vaccine. Latency cannot be properly assessed since no vaccination date nor onset date of the event were provided. No cause of death was reported, and it is unknown if an autopsy was made. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This fatal spontaneous case concerns a male patient of unknown age, with no medical history reported, who received a dose of mRNA-1273 and died. According to the reporter, the patient died isolated in long term care after receiving moderna vaccine. Latency cannot be properly assessed since no vaccination date nor onset date of the event were provided. No cause of death was reported, and it is unknown if an autopsy was made. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_05948716 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221014 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2022A328426()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220922 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20221014 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2022A328426

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) GMIP ID MC Canada AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** 10314763 [redacted] CA-AstraZeneca-2022A328426

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 59 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05948716 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Arrhythmia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
	ASKU	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 1		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
	ASKU	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 2		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ARRHYTHMIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Arrhythmia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Arrhythmia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer concerning a male patient of Unknown ethnic origin (age 59 years).

No medical history was reported and No concomitant products were reported.

On an unknown date, the patient received first dose of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml #dose1 (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number ASKU), via intramuscular route, for an unknown indication. On an unknown date, the patient received second dose of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml #dose2 (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number ASKU), via intramuscular route, for an unknown indication.

On an unknown date, the patient experienced arrhythmia (preferred term: Arrhythmia).

It was unknown if any action was taken with both the doses of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml

The patient died from the event arrhythmia on an unspecified date.

An autopsy was not performed. The cause of death was arrhythmia.

The reporter assessed the event of arrhythmia to be serious due to seriousness criteria of death.

All required follow up attempts have been completed to obtain the Lot / batch number for Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml, however the Lot / batch number was not received

Summary of follow-up information received by Astrazeneca/MedImmune on 14-Oct-2022 from consumer via spontaneous source: Lot / Batch number updated to ASKU. Lot / Batch number statement updated. Narrative amended. Minor correction on 14-Oct-2022: Autopsy performed was updated from unk to No.CAUSE OF DEATH: ARRHYTHMIA

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Arrhythmia is not listed in the company core data sheet of AZD1222. Due to limited information on circumstances leading to the event, onset date of event,relevant medical and family history,concurrent conditions, concomitant medications, date of vaccination, possible risk factors, etiological and diagnostic work up, autopsy details, the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Arrhythmia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210824 CCYYMMDD
	HC Initial Received Date:	20210824 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR-20210824212537_299273()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
		Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Community -

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Female	160 Centimeter	50 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			18 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Yes

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Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	EY0578	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
frequencytext:1		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NOTICED DECEASED IN HER BED, FOR UNKNOWN REASON

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Found dead (cause undetermined)		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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Canada Vigilance AER#:	000964567 (0)	Page#4

Summary (B.5)

Case narrative (B.5.1)

Not sure if the death relates to the pfizer vaccine or not, since it happens 17 days after the vaccine taken, it's necessary to report.

Dhpr log details:
Safety Report ID: CA-DHPR-20210824212537_299273
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20210824
First Name: [redacted]
Last Name: [redacted]
Telephone: [redacted]
Ext.:
Address: [redacted]
City: [redacted]
Province/Territory: [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization: [redacted]
Reporter Type: Physician

Patient ID: [redacted]
Age: 18 Year(s)
Sex: Female
Height: cm
Weight:
Med History: 18 yo healthy female, no any known medical condition, no mental health disease, no smoking, no alcohol, no drugs, average height (about 160cm) and weight (50kg).
Allergies: none

Serious Death: Yes
Date of Death: 2021[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Died
Reaction Start Date:
Reaction End Date:
Reaction Description: 18yo healthy female was noticed deceased in her bed by her parents on 10am of [redacted] 2021 for unknown reason. She was happily doing activities with family by 11pm on [redacted] before her bedtime. Autopsy was taken, but there was no conclusion. She had first dose of pfizer vaccine on [redacted] 2021.

Suspect Product 1
DIN #/NPN #:
Product Name: pfizer-biontech covid 19 vaccine mRNA
Strength:
Strength other:
Dosage form:
Manufacturer: pfizer-biontech
Lot #: lot # EY0578
Expiry date:
Product start date: 2021[redacted]
Product end date: 2021[redacted]
Dose:
Frequency: 1
Route of administration: Intramuscular
Route of administration - Other:
Indication: [redacted] health unit
Reported to Mfr:
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Not applicable
Dechallenge: N/A
Rechallenge: N/A

Concomitants: none.
Test/Lab results narrative: none.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

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Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Non-smoker		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Abstains from alcohol		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Abstains from recreational drugs		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

Relevant medical history/ Concurrent conditions text (B.1.7.2)

18 yo healthy female, no any known medical condition, no mental health disease, no smoking, no alcohol, no drugs, average height (about 160cm) and weight (50kg).
Allergies:none

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

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Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) [redacted]	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) [redacted]
Reporter organization (A.2.1.2a) [redacted]		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) [redacted]			
Reporter city (A.2.1.2d) [redacted]		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f) [redacted]	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Canada Vigilance AER#:	000964567 (0)	

Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05951748 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221031 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-PV202200071037(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220922 CCYYMMDD	20221031 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-PV202200071037

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-PV202200071037

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
7 Minutes	7 Minutes	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
7 Minutes	7 Minutes	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP), Program ID: [redacted]

A female patient received BNT162b2 (COMIRNATY), on [redacted]2022 at 12:31 as dose number unknown (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEATH (death) with onset [redacted]022 at 12:38, outcome "fatal", described as "died". The patient date of death was [redacted]2022. The reported cause of death was unknown.
Clinical course: Patient died suddenly in a drug store allegedly within minutes of receiving her COVID-19 booster shot. She texted her daughter at 12:31 p.m. and said she was waiting her 15 min. At 12:38 p.m. she was unconscious in the drug store. They were saying in the store that it was about seven minutes after patient got the booster shot that she collapsed on the floor. A spokesperson said that patient's death was from natural causes. Patient had no health conditions and reporter believed that if she did not get Covid shot she would be here with them at the time of this report. Patient had been pro-vaccine, getting all of the required COVID-19 shots.

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.

Amendment: This follow-up report is being submitted to notify that the initial information for this case was first received by the Company on 22Sep2022 and not on 26Sep2022 as previously reported. Due to safety database technical limitations, the field 'Initial Receipt Date' (i.e.Company first awareness date) can no longer be modified.

Follow-up (31Oct 2022): Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_05977659 (5)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221212 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2022034554(4)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2022[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 202[redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-GLAXOSMITHKLINE-CA2022034554

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) 01052547635	**Duplicate Case identifiers (A.1.11.2)** CA-GLAXOSMITHKLINE-CA2022034554

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) E2B_03305971, (2) , (2) E2B_03369525, (2) , (2) E2B_03305971, (2) , (2) E2B_03369525, (2) , (2) E2B_03305971, (2) , (2) E2B_03369525, (2) , (2) E2B_03305971, (2) , (2) E2B_03369525, (2) , (2) E2B_03305971, (2) , (2) E2B_03369525

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - GLAXOSMITHKLINE

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 76 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	YK7H	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg, Z Every 4 weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0 26.0	Eosinophilic asthma Eosinophilic asthma Eosinophilic asthma
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
ExpDT=30-JUN-2023		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)
Suspect	**INFLUENZA VACCINES**
Active Substance names (B.4.k.2.2)	
influenza virus vaccine	
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**
Canada	
Holder and authorization/application no. of drug (B.4.k.4)	
Country of authorization/application: Canada	
Structured dosage info (B.4.k.5)	
Dosage text (B.4.k.6)	

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Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Burning sensation in eye	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug dose administration interval too long	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	High pulse rate	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hospitalization	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Injection site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 prophylaxis
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CEPHALEXIN	
Active Substance names (B.4.k.2.2)		
cephalexin		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
500 Milligram		
Dosage text (B.4.k.6)		
500 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2022[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Dosage maintained		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	AZITHROMYCIN	
Active Substance names (B.4.k.2.2)		
azithromycin		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
250 Milligram		
Dosage text (B.4.k.6)		
250 mg 3x/week		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PREDNISONE	
Active Substance names (B.4.k.2.2)		
prednisone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
50 Milligram		
Dosage text (B.4.k.6)		
50 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
2022[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT HAS PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)

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26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHE IS IN HOSPITAL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hospitalization		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Hospitalisation		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LUNG INFECTION,PATIENT HOSPITALIZED DUE TO PNEUMONIA LAST [redacted] TO [redacted]

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lung infection		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHORTNESS OF BREATH (SOB) ON EXERTION/PATIENT SOB ON EXERTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Exertional dyspnea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Dyspnoea exertional		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Recovering/resolving	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW O2 SAT READING OSCILLATING FROM 80% TO 93% W/ 1.5 LPM RA,VERY LOW UNSTABLE O2 60 TO 64% / VERY LOW O2 SATURATION OSCILLATING AT 56MMOL/L / HAD 50% O2 SATURATION LAST WEEK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Oxygen saturation decreased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Oxygen saturation decreased		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
573 Days		Recovering/resolving	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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CHEST PAIN 4 ON 10 LAST WEEK BUT EVENTUALLY WENT AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chest pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Chest pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Recovered/resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT REPORTED FELT PAIN AT INJECTION SITE / BURNING SENSATION AT START OF INJECTION BUT RESOLVED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Injection site pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Injection site pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIARRHEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Diarrhea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Diarrhoea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WOUND DRESSING ON LEFT SMALL & 2ND FINGER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Wound
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Wound

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HIGH BP 190/123

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Increased blood pressure
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Blood pressure increased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

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	2022[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
677 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BURNING SENSATION TIME TO TIME FROM BOTH EYES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Burning sensation in eye		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Eye irritation		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SORE THROAT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Sore throat		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Oropharyngeal pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HIGH PULSE RATE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	High pulse rate		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Heart rate increased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
820 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT MISSED SCHEDULED DOSE OF INJECTION ON [redacted] 2022. PATIENT'S CURRENT INJECTION [redacted] 2022) OUTSIDE THE 7-DAY TREATMENT WINDOW. LAST DOSE OF DRUG WAS ADMINISTERED ON [redacted] 2022.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Drug dose administration interval too long		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Inappropriate schedule of product administration		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted] CCYYMMDD	202[redacted] CCYYMMDD	1 Days
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
820 Days		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This case was reported by a consumer via patient support programs and described the occurrence of unknown cause of death in a 76-year-old female patient who received ranibizumab solution for injection in pre-filled syringe (batch

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death in a 70 year old female patient who received mepolizumab solution for injection in pre-filled syringe (batch number YK7H, expiry date 30th June 2023) for eosinophilic asthma.

Co-suspect products included mepolizumab pre-filled syringe device injection syringe (batch number YK7H, expiry date 30th June 2023) for eosinophilic asthma, mepolizumab solution for injection in pre-filled syringe (batch number LK8K, expiry date 30th November 2023) for eosinophilic asthma, mepolizumab pre-filled syringe device injection syringe (batch number LK8K, expiry date 30th November 2023) for eosinophilic asthma, mepolizumab solution for injection in pre-filled syringe (batch number GH8D, expiry date 28th February 2025) for eosinophilic asthma, mepolizumab pre-filled syringe device injection syringe (batch number GH8D, expiry date 28th February 2025) for eosinophilic asthma, Flu Seasonal QIV Quebec (Canadian influenza vaccine Quadrivalent 2022-2023 season) for prophylaxis and covid-19 vaccine for covid-19 prophylaxis.

Concurrent medical conditions included allergy to antibiotic (Bactrim). Additional subject notes included no patient history. Concomitant products included cefalexin (Cephalexin), azithromycin and prednisone.

On [redacted] 2020, the patient started mepolizumab (subcutaneous) 100 mg (every 4 weeks), mepolizumab pre-filled syringe device, mepolizumab (subcutaneous) 100 mg (every 4 weeks), mepolizumab pre-filled syringe device, mepolizumab (subcutaneous) 100 mg (every 4 weeks) and mepolizumab pre-filled syringe device. On an unknown date, the patient received Canadian influenza vaccine Quadrivalent 2022-2023 season and covid-19 vaccine at an unknown dose and frequency. On [redacted] 2022, 573 days after starting mepolizumab, mepolizumab pre-filled syringe device, mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device and not applicable after receiving Canadian influenza vaccine Quadrivalent 2022-2023 season, the patient experienced oxygen saturation decreased. In [redacted] 2022, the patient experienced chest pain. On [redacted] 2022, the patient experienced increased blood pressure. On [redacted] 2022, the patient experienced high pulse rate and drug dose administration interval too long. On an unknown date, the patient experienced unknown cause of death (serious criteria death and GSK medically significant), hospitalization (serious criteria hospitalization), lung infection (serious criteria hospitalization and GSK medically significant), exertional dyspnea, injection site pain, diarrhea, wound, burning sensation in eye and sore throat. The subject was treated with salbutamol (Ventolin) and amoxicillin + clavulanate potassium (Amoxiclav). Mepolizumab was continued with no change. Mepolizumab was continued with no change. Mepolizumab was continued with no change. On [redacted] 2022, the outcome of the drug dose administration interval too long was unknown. On an unknown date, the outcome of the unknown cause of death was fatal and the outcome of the hospitalization was not recovered/not resolved and the outcome of the increased blood pressure, high pulse rate, lung infection, injection site pain, diarrhea, wound, burning sensation in eye and sore throat were unknown and the outcome of the oxygen saturation decreased and exertional dyspnea were recovering/resolving and the outcome of the chest pain was recovered/resolved. The reported cause of death was unknown cause of death.

It was unknown if the reporter considered the unknown cause of death, hospitalization, exertional dyspnea, oxygen saturation decreased, chest pain, injection site pain, diarrhea, wound, increased blood pressure, burning sensation in eye, sore throat and high pulse rate to be related to mepolizumab, mepolizumab pre-filled syringe device, mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device. The reporter considered the lung infection to be unrelated to mepolizumab, mepolizumab pre-filled syringe device, mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device. It was unknown if the reporter considered the unknown cause of death, lung infection and high pulse rate to be related to Canadian influenza vaccine Quadrivalent 2022-2023 season. This report is made by GSK without prejudice and does not imply any admission or liability for the incident or its consequences.

Linked case(s) involving the same patient:CA2020AMR099985, CA2020AMR127544, CA2021AMR062591, CA2021AMR207444, CA2021AMR250124

GSK Receipt Date: [redacted] 2022
Reporter's Comments: Post infusion report: Patient shortness of breath on exertion. Took ventolin as needed. Patient said she felt better when she was sitting down. Injection well tolerated. No other issues. Patient stable at departure. No further information provided. Other products were unknown. Patient took Mepolizumab as Nucala every 4 weeks.

Follow-up information received on [redacted] 2022. This follow-up was considered significant. Reporter's Comments: This case received from Nucala Patient Support Program (Vista). Post infusion report: Patient Shortness of breath on exertion gradually stabilized. Low Oxygen saturation reading oscillating from 80 percent to 93 percent with 1.5 liters per minute oxygen. Patient took Ventolin earlier. Patient stated she had undergone an ENT (ear, nose, and throat) /ORL exam [redacted] 2022. Injection tolerated well. No issues. Patient stable at departure. Patient received Nucala for severe eosinophilic asthma. No further information provided.
Summary of Changes: Allergy of Bactrim and event of oxygen saturation decreased added. Outcome of Exertional dyspnea updated.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Patient SOB(shortness of breath) on exertion. O2 oscillating from 81% to 92% w/ 1.5 LPM O2, stabilizing at rest. Patient denied any other adverse event since last treatment. Patient said decreased O2 happens all the time even with small effort like going to the bathroom, etc. Injection well tolerated. No voiced complaints. Patient stable at my departure. No further information provided.
Summary of changes: added lab data, updated event verbatim..

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Case was received via Nucala Patient Support Program (Vista). Post infusion report: Patient stated she had chest pain 4 on 10 last week but eventually went away. Patient had 4th dose Covid19 Vaccine on 22ndApr. Oxygen saturation oscillating between 88percent to 91percent with 1 1/2 LPM O2 after walking 4 steps & resting for 5 mins. Patient said she felt fine. Injection well tolerated. No issues. Advised to seek prn. No further information provided. It was unknown if the reporter considered the exertional dyspnea, oxygen saturation decreased and chest pain to be related to covid-19 vaccine.
Summary of changes: Product details, event details and lab data, updated.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's comment: Patient stable when nurse arrived. Patient reported felt pain at injection site the evening after last tx, added pain did not last long. Patient said 2 weeks ago, she had diarrhea that lasted a day. Band-aid dressing noted on left small finger and second finger. Patient uncertain what caused small wound. Injection well tolerated. No immediate site reaction. Patient was stable.
Summary of changes: Injection site pain, diarrhea and Wound event was added.

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Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Post infusion reported that patient Shortness Of Breath on exertion walking 3 meters around room. Patient reported had high Blood Pressure 190/123 and very low O2 66 percent RA last [redacted] after taking more than 5 minutes shower from new caregiver. Patient said EMS was not called as vitals gradually stabilized. Patient seen Ophthalmologist [redacted] 2022 & awaiting eye surgery. Patient said been two and half years feeling burning sensation time to time from both eyes. Patient complaint of burning sensation at start of injection but resolved. Patient stable. No further information provided.
Summary of changes: lab details added, Added event details for Increased blood pressure and eye irritation.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Post Injection report: Patient reported past week she experienced very low unstable O2 between 60 to 64 percent but gradually stabilized after increasing O2 aid from 1.5 percent to 2 percent LPM. Patient said she was Rx lung exercises by Dre with a Respiratory Therapist via online under Pulmonary Rehab Program. Patient said Dr was aware. Injection well tolerated. No further information provided.
Summary of Changes: Updated event term and narrative.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: [redacted] 2022 post injection report patient stable when nurse arrived. Patient reported had very low O2 saturation oscillating at 56mmol/L around 2 weeks ago. Patient had prednisone 50mg x 10 days since [redacted] 2022 and 5mg x 5 days thereafter part of her action plan. Patient stated she was benefiting from nucala as she had not been hospitalized since past year. Patient added she feels good doing her virtual lung exercises with therapists. Injection well tolerated. Patient stable. No further information provided.
Summary of Changes: Narrative updated.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Case was received via [redacted] Nucala Patient Support Program (Vista). Post infusion report: Patient stable when nurse arrived. Sister present. Patient stated currently on antibiotic Amoxiclav 875-125mg x 5 days since [redacted] and Prednisone 50mg x 5 days since [redacted] due to lung infection. Patient added she currently has sore throat but no fever. Patient added she was Covid negative. Patient reported had 50percent Oxygen saturation last week. Patient said she increased O2 to 2LPM past 2 weeks. Injection well tolerated. No immediate site reaction. Patient stable at my depart. No further information provided. It was unknown if the reporter considered the lung infection and sore throat to be related to covid-19 vaccine.
Summary of Changes: Lab data, product and event details updated.

Follow-up information received on [redacted] 2022
Reporter's Comments: This case was received from Nucala patient support program (Vista). Patient's caregiver called to cancel patient's next appointment as she was in hospital. Reporter was unsure if patient will be discharged before [redacted] and that she would like to cancel delivery of medication. Patient's caregiver stated they would call again to reschedule. Other products unknown. Did not consent to contact. No further information provided.
Summary of Changes: Event added

Follow-up information received on [redacted] 2022.
Reporter's Comments: This report was received by Site [redacted] - Nucala Patient Support Program (Vista). Post infusion report. Patient was stable when nurse arrived. Patient's niece was present, Niece said patient hospitalized due to pneumonia last [redacted] 2022 to [redacted] 2022. Patient said continuing Cephalexin 500mg since [redacted] 2022 finishing [redacted] 2022. Patient had regular Azithromycin 250 mg. she currently take 3/week for preventive measures. Patient said had 5th dose Covid-19Vaccine and Flu Vaccine around [redacted] 2022. High pulse noted 100bpm stabilized at 89bpm after 15 minutes post treatment. Injection well tolerated. No immediate site reaction. Patient was stable. Patient missed scheduled dose of injection on [redacted] 2022. Patient's current injection [redacted] 2022) outside the 7-day treatment window. Last dose of drug was administered on [redacted] 2022. No further information provided.
Summary of Changes: Products tab, patient tab, events tab and narrative got updated.

The case was amended on [redacted] 2022: The product start date was amended Co-suspect product Canadian influenza vaccine Quadrivalent 2022-2023 season start date [redacted] 2022 and Covid-19 vaccine start date [redacted] 2022 were removed from structured field and kept in narrative only.

Follow-up information received on [redacted] 2022
Reporter's Comment: This report was received by Site [redacted] - Nucala Patient Support Program (Vista). Post infusion report. Email received stated the patient had passed away (death NOS). No further information provided.
Summary of Changes: Patient tab, product tab, Event tab and narrative updated.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Death,Hospitalisation and Pneumonia are unlisted events which are considered unrelated to GSK drug Mepolizumab and Mepolizumab prefilled syringe device.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2022[redacted] CCYYMMDD	Laboratory test	Unknown	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
unknown			Yes

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Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
202[redacted] CCYYMMDD	Oxygen saturation	1.5	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
l/min			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2022[redacted] CCYYMMDD	Oxygen saturation	93	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2022[redacted] CCYYMMDD	Oxygen saturation	1.5	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
l/min			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2022[redacted] CCYYMMDD	Oxygen saturation	88	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2022[redacted] CCYYMMDD	Oxygen saturation	91	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
202[redacted] CCYYMMDD	Blood pressure	BP 190/123	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
unknown	unk	unk	No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2022[redacted] CCYYMMDD	Oxygen saturation	66	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2022[redacted] CCYYMM	Oxygen saturation	50	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2022 CCYY	Oxygen saturation	very low unstable O2 between 60 to 64 percent but	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	COVID-19 virus test	Negative value	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
unknown	unk	unk	No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Oxygen saturation	80	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Oxygen saturation	81	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Oxygen saturation	92	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

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%			Yes

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Pulse rate	100	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
beats/min			Yes

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Pulse rate	89	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
beats/min			Yes

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Allergy to antibiotic	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	

Comments (B.1.7.1g)
Bactrim

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)
no patient history

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1) Mepolizumab Patient Support Program		Project No	
Sponsor Study no. (A.2.3.2) Mepolizumab PSP		Observed study type (A.2.3.3) Other studies	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year
PRIVACY	Canada				76	F			

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

PATIENT HAS PASSED AWAY (Unknown cause of death (10063378), Death (10011906)) - Fatal
Protocol relatedness:
As per reporter:
As per company:

SHE IS IN HOSPITAL (Hospitalization (10074101), Hospitalisation (10054112)) - Not recovered/not resolved
Protocol relatedness:
As per reporter:
As per company:

LUNG INFECTION, PATIENT HOSPITALIZED DUE TO PNEUMONIA LAST [redacted] TO [redacted] (Lung infection (10061229), Pneumonia (10035664)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [X] PATIENT DIED
- [X] INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- [ ] INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [X] OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

MEPOLIZUMAB (mepolizumab), YK7H

Cont...

20. DID REACTION ABATE AFTER STOPPING DRUG? [ ] YES [ ] NO [ ] NA

15. DAILY DOSE(S)

100 mg, Z every 4 weeks (100 mg)

16. ROUTE(S) OF ADMINISTRATION

Subcutaneous

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? [ ] YES [ ] NO [ ] NA

17. INDICATION(S) FOR USE

[10068462 - Eosinophilic asthma]
[10068462 - Eosinophilic asthma]

Cont...

18. THERAPY DATES (from/to)

[redacted] 2020 -

19. THERAPY DURATION

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

CEPHALEXIN (cephalexin) (NOT SPECIFIED)	[redacted] 2022 -	500 mg (500 mg)
AZITHROMYCIN (azithromycin) (NOT SPECIFIED)		250 mg 3x/week (250 mg)

Cont...

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

no patient history

Concurrent Disease:
[10082424 - Allergy to antibiotic] (Continuing: Yes): Bactrim

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

HealthCanada_Post_Market
Canada

Initial Reporter:
PRIVACY
Canada

EudraCT no :
Study no : Mepolizumab_PSP
Center no :
Cont...

24b. MFR. CONTROL NO.

EZB_05977659

24c. DATE RECEIVED BY MANUFACTURER

[redacted] 2022

24d. REPORT SOURCE

[ ] STUDY [ ] LITERATURE [ ] AUTHORITY
[X] HEALTH PROFESSIONAL [ ] OTHER

DATE OF THIS REPORT

05/10/2023

25a. REPORT TYPE

[ ] INITIAL [X] FOLLOW UP

Cont... = Continuation attached sheet(s)

DRAFT

ATIA - 19(1)

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Continuation Sheet for CIOMS report **Mfr. Control No. :E2B_05977659**

Reaction Information (Cont...)

Seq. No. : 1
Reaction : PATIENT MISSED SCHEDULED DOSE OF INJECTION ON [redacted] 2022. PATIENT'S CURRENT INJECTION [redacted] 2022) OUTSIDE THE 7-DAY TREATMENT WINDOW. LAST DOSE OF DRUG WAS ADMINISTERED ON [redacted] 2022. (Drug dose administration interval too long (10064320), Inappropriate schedule of product administration (10081572))
Duration : 1 D

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

SHORTNESS OF BREATH (SOB) ON EXERTION/PATIENT SOB ON EXERTION (Exertional dyspnea (10055548), Dyspnoea exertional (10013971)) - Recovering/resolving
Protocol relatedness:
As per reporter:
As per company:

LOW O2 SAT READING OSCILLATING FROM 80% TO 93% W/ 1.5 LPM RA,VERY LOW UNSTABLE O2 60 TO 64% / VERY LOW O2 SATURATION OSCILLATING AT 56MMOL/L / HAD 50% O2 SATURATION LAST WEEK (Oxygen saturation decreased (10033318), Oxygen saturation decreased (10033318)) - Recovering/resolving
Protocol relatedness:
As per reporter:
As per company:

CHEST PAIN 4 ON 10 LAST WEEK BUT EVENTUALLY WENT AWAY (Chest pain (10008479), Chest pain (10008479)) - Recovered/resolved
Protocol relatedness:
As per reporter:
As per company:

PATIENT REPORTED FELT PAIN AT INJECTION SITE / BURNING SENSATION AT START OF INJECTION BUT RESOLVED (Injection site pain (10022086), Injection site pain (10022086)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

DIARRHEA (Diarrhea (10012727), Diarrhoea (10012735)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

WOUND DRESSING ON LEFT SMALL & 2ND FINGER (Wound (10052428), Wound (10052428)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

HIGH BP 190/123 (Increased blood pressure (10021655), Blood pressure increased (10005750)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

BURNING SENSATION TIME TO TIME FROM BOTH EYES (Burning sensation in eye (10006786), Eye irritation (10015946)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

SORE THROAT (Sore throat (10041367), Oropharyngeal pain (10068319)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

HIGH PULSE RATE (High pulse rate (10020081), Heart rate increased (10019303)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

PATIENT MISSED SCHEDULED DOSE OF INJECTION ON [redacted] 2022. PATIENT'S CURRENT INJECTION [redacted] 2022) OUTSIDE THE 7-DAY TREATMENT WINDOW. LAST DOSE OF DRUG WAS ADMINISTERED ON [redacted] 2022. (Drug dose administration interval too long (10064320), Inappropriate schedule of product administration (10081572)) - Unknown
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Fatal

This case was reported by a consumer via patient support programs and described the occurrence of unknown cause of death in a 76-year-old female patient who received mepolizumab solution for injection in pre-filled syringe (batch number YK7H, expiry date 30th June 2023) for eosinophilic asthma.

Co-suspect products included mepolizumab pre-filled syringe device injection syringe (batch number YK7H, expiry date 30th June 2023) for eosinophilic asthma, mepolizumab solution for injection in pre-filled syringe (batch number LK8K, expiry date 30th November 2023) for eosinophilic asthma, mepolizumab pre-filled syringe device injection syringe (batch number LK8K, expiry date 30th November 2023) for eosinophilic asthma, mepolizumab solution for injection in pre-filled syringe (batch number GH8D, expiry date 28th February 2025) for eosinophilic asthma, mepolizumab pre-filled syringe device injection syringe (batch number GH8D, expiry date 28th February 2025) for eosinophilic asthma, Flu Seasonal QIV Quebec (Canadian influenza vaccine Quadrivalent 2022-2023 season) for prophylaxis and covid-19 vaccine for covid-19 prophylaxis.

DRAFT

ATIA - 19(1)

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Continuation Sheet for CIOMS report **Mfr. Control No. :E2B_05977659**

Concurrent medical conditions included allergy to antibiotic (Bactrim). Additional subject notes included no patient history. Concomitant products included cefalexin (Cephalexin), azithromycin and prednisone.

On [redacted] 2020, the patient started mepolizumab (subcutaneous) 100 mg (every 4 weeks), mepolizumab pre-filled syringe device, mepolizumab (subcutaneous) 100 mg (every 4 weeks), mepolizumab pre-filled syringe device, mepolizumab (subcutaneous) 100 mg (every 4 weeks) and mepolizumab pre-filled syringe device. On an unknown date, the patient received Canadian influenza vaccine Quadrivalent 2022-2023 season and covid-19 vaccine at an unknown dose and frequency. On [redacted] 2022, 573 days after starting mepolizumab, mepolizumab pre-filled syringe device, mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device and not applicable after receiving Canadian influenza vaccine Quadrivalent 2022-2023 season, the patient experienced oxygen saturation decreased. In [redacted] 2022, the patient experienced chest pain. On [redacted] 2022, the patient experienced increased blood pressure. On [redacted] 2022, the patient experienced high pulse rate and drug dose administration interval too long. On an unknown date, the patient experienced unknown cause of death (serious criteria death and GSK medically significant), hospitalization (serious criteria hospitalization), lung infection (serious criteria hospitalization and GSK medically significant), exertional dyspnea, injection site pain, diarrhea, wound, burning sensation in eye and sore throat. The subject was treated with salbutamol (Ventolin) and amoxicillin + clavulanate potassium (Amoxiclav). Mepolizumab was continued with no change. Mepolizumab was continued with no change. Mepolizumab was continued with no change. On [redacted] 2022, the outcome of the drug dose administration interval too long was unknown. On an unknown date, the outcome of the unknown cause of death was fatal and the outcome of the hospitalization was not recovered/not resolved and the outcome of the increased blood pressure, high pulse rate, lung infection, injection site pain, diarrhea, wound, burning sensation in eye and sore throat were unknown and the outcome of the oxygen saturation decreased and exertional dyspnea were recovering/resolving and the outcome of the chest pain was recovered/resolved. The reported cause of death was unknown cause of death.

It was unknown if the reporter considered the unknown cause of death, hospitalization, exertional dyspnea, oxygen saturation decreased, chest pain, injection site pain, diarrhea, wound, increased blood pressure, burning sensation in eye, sore throat and high pulse rate to be related to mepolizumab, mepolizumab pre-filled syringe device, mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device. The reporter considered the lung infection to be unrelated to mepolizumab, mepolizumab pre-filled syringe device, mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device. It was unknown if the reporter considered the unknown cause of death, lung infection and high pulse rate to be related to Canadian influenza vaccine Quadrivalent 2022-2023 season. This report is made by GSK without prejudice and does not imply any admission or liability for the incident or its consequences.

Linked case(s) involving the same patient:CA2020AMR099985, CA2020AMR127544, CA2021AMR062591, CA2021AMR207444, CA2021AMR250124

GSK Receipt Date: [redacted] 2022
Reporter's Comments: Post infusion report: Patient shortness of breath on exertion. Took ventolin as needed. Patient said she felt better when she was sitting down. Injection well tolerated. No other issues. Patient stable at departure. No further information provided. Other products were unknown. Patient took Mepolizumab as Nucala every 4 weeks.

Follow-up information received on [redacted] 2022. This follow-up was considered significant. Reporter's Comments: This case received from Nucala Patient Support Program (Vista). Post infusion report: Patient Shortness of breath on exertion gradually stabilized. Low Oxygen saturation reading oscillating from 80 percent to 93 percent with 1.5 liters per minute oxygen. Patient took Ventolin earlier. Patient stated she had undergone an ENT (ear, nose, and throat) /ORL exam [redacted] 2022. Injection tolerated well. No issues. Patient stable at departure. Patient received Nucala for severe eosinophilic asthma. No further information provided.
Summary of Changes: Allergy of Bactrim and event of oxygen saturation decreased added. Outcome of Exertional dyspnea updated.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Patient SOB(shortness of breath) on exertion. O2 oscillating from 81% to 92% w/ 1.5 LPM O2, stabilizing at rest. Patient denied any other adverse event since last treatment. Patient said decreased O2 happens all the time even with small effort like going to the bathroom, etc. Injection well tolerated. No voiced complaints. Patient stable at my departure. No further information provided.
Summary of changes: added lab data, updated event verbatim..

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Case was received via Nucala Patient Support Program (Vista). Post infusion report: Patient stated she had chest pain 4 on 10 last week but eventually went away. Patient had 4th dose Covid19 Vaccine on [redacted] Oxygen saturation oscillating between 88percent to 91percent with 1 1/2 LPM O2 after walking 4 steps & resting for 5 mins. Patient said she felt fine. Injection well tolerated. No issues. Advised to seek prn. No further information provided. It was unknown if the reporter considered the exertional dyspnea, oxygen saturation decreased and chest pain to be related to covid-19 vaccine.
Summary of changes: Product details, event details and lab data, updated.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's comment: Patient stable when nurse arrived. Patient reported felt pain at injection site the evening after last tx, added pain did not last long. Patient said 2 weeks ago, she had diarrhea that lasted a day. Band-aid dressing noted on left small finger and second finger. Patient uncertain what caused small wound. Injection well tolerated. No immediate site reaction. Patient was stable.
Summary of changes: Injection site pain, diarrhea and Wound event was added.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Post infusion reported that patient Shortness Of Breath on exertion walking 3 meters around room. Patient reported had high Blood Pressure 190/123 and very low O2 66 percent RA last [redacted] after taking more than 5 minutes shower from new caregiver. Patient said EMS was not called as vitals gradually stabilized. Patient seen Ophthalmologist [redacted] 2022 & awaiting eye surgery. Patient said been two and half years feeling burning sensation time to time from both eyes. Patient complaint of burning sensation at start of injection but resolved. Patient stable. No further information provided.
Summary of changes: lab details added, Added event details for Increased blood pressure and eye irritation.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Post Injection report: Patient reported past week she experienced very low unstable O2 between 60 to 64 percent but gradually stabilized after increasing O2 aid from 1.5 percent to 2 percent LPM. Patient said she was Rx lung exercises by Dre with a Respiratory Therapist via online under Pulmonary Rehab Program. Patient said Dr was aware. Injection well tolerated. No further information provided.
Summary of Changes: Updated event term and narrative.

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Continuation Sheet for CIOMS report **Mfr. Control No. :E2B_05977659**

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: 02 Sep 2022 post injection report patient stable when nurse arrived. Patient reported had very low O2 saturation oscillating at 56mmol/L around 2 weeks ago. Patient had prednisone 50mg x 10 days since [redacted] 2022 and 5mg x 5 days thereafter part of her action plan. Patient stated she was benefiting from nucala as she had not been hospitalized since past year. Patient added she feels good doing her virtual lung exercises with therapists. Injection well tolerated. Patient stable. No further information provided.
Summary of Changes: Narrative updated.

Follow-up information received on [redacted] 2022. This follow-up was considered significant.
Reporter's Comments: Case was received via [redacted], Nucala Patient Support Program (Vista). Post infusion report: Patient stable when nurse arrived. Sister present. Patient stated currently on antibiotic Amoxiclav 875-125mg x 5 days since [redacted] and Prednisone 50mg x 5 days since [redacted] due to lung infection. Patient added she currently has sore throat but no fever. Patient added she was Covid negative. Patient reported had 50percent Oxygen saturation last week. Patient said she increased O2 to 2LPM past 2 weeks. Injection well tolerated. No immediate site reaction. Patient stable at my depart. No further information provided. It was unknown if the reporter considered the lung infection and sore throat to be related to covid-19 vaccine.
Summary of Changes: Lab data, product and event details updated.

Follow-up information received on [redacted] 2022
Reporter's Comments: This case was received from Nucala patient support program (Vista). Patient's caregiver called to cancel patient's next appointment as she was in hospital. Reporter was unsure if patient will be discharged before October 28th and that she would like to cancel delivery of medication. Patient's caregiver stated they would call again to reschedule. Other products unknown. Did not consent to contact. No further information provided.
Summary of Changes: Event added

Follow-up information received on [redacted] 2022.
Reporter's Comments: This report was received by Site [redacted] - Nucala Patient Support Program (Vista). Post infusion report. Patient was stable when nurse arrived. Patient's niece was present. Niece said patient hospitalized due to pneumonia last [redacted] 2022 to [redacted] 2022. Patient said continuing Cephalexin 500mg since [redacted] 2022 finishing [redacted] 2022. Patient had regular Azithromycin 250 mg. she currently take 3/week for preventive measures. Patient said had 5th dose Covid-19Vaccine and Flu Vaccine around [redacted] 2022. High pulse noted 100bpm stabilized at 89bpm after 15 minutes post treatment. Injection well tolerated. No immediate site reaction. Patient was stable. Patient missed scheduled dose of injection on [redacted] 2022. Patient's current injection [redacted] 2022) outside the 7-day treatment window. Last dose of drug was administered on [redacted] 2022. No further information provided.
Summary of Changes: Products tab, patient tab, events tab and narrative got updated.

The case was amended on [redacted] 2022: The product start date was amended Co-suspect product Canadian influenza vaccine Quadrivalent 2022-2023 season start date [redacted]-2022 and Covid-19 vaccine start date [redacted] 2022 were removed from structured field and kept in narrative only.

Follow-up information received on [redacted] 2022
Reporter's Comment: This report was received by Site [redacted] - Nucala Patient Support Program (Vista). Post infusion report. Email received stated the patient had passed away (death NOS). No further information provided.
Summary of Changes: Patient tab, product tab, Event tab and narrative updated.

Company Remarks (Sender's comments) (Cont...)

Death,Hospitalisation and Pneumonia are unlisted events which are considered unrelated to GSK drug Mepolizumab and Mepolizumab prefilled syringe device.

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No.	:	1
Drug	:	MEPOLIZUMAB(mepolizumab),YK7H
Daily Dose	:	2) 100 mg, Z every 4 weeks (100 mg) 3) 100 mg, Z Every 4 weeks (100 mg)
Route of Admin	:	1) Subcutaneous 2) Subcutaneous 3) Subcutaneous
Indication for use	:	3) [10068462 - Eosinophilic asthma]
Therapy Dates/Duration	:	2) [redacted] 2020 - 3) [redacted] 2020 -

Causality

1) LOW O2 SAT READING OSCILLATING FROM 80% TO 93% W/ 1.5 LPM RA,VERY LOW UNSTABLE O2 60 TO 64% / VERY LOW O2 SATURATION OSCILLATING AT 56MMOL/L / HAD 50% O2 SATURATION LAST WEEK (Oxygen saturation decreased (10033318), Oxygen saturation decreased (10033318))
   Action(s) taken with drug : Dosage maintained
2) HIGH BP 190/123 (Increased blood pressure (10021655), Blood pressure increased (10005750))
   Action(s) taken with drug : Dosage maintained
3) HIGH PULSE RATE (High pulse rate (10020081), Heart rate increased (10019303))
   Action(s) taken with drug : Dosage maintained
4) PATIENT MISSED SCHEDULED DOSE OF INJECTION ON [redacted] 2022. PATIENT'S CURRENT INJECTION [redacted] 2022) OUTSIDE THE 7-DAY TREATMENT WINDOW. LAST DOSE OF DRUG WAS ADMINISTERED ON [redacted] 2022. (Drug dose administration interval too long (10064320), Inappropriate schedule of product administration (10081572))
   Action(s) taken with drug : Dosage maintained

Seq.No.	:	2
Drug	:	INFLUENZA VACCINES(influenza virus vaccine)(NOT SPECIFIED)
Route of Admin	:	1) Unknown
Indication for use	:	1) [10036898 - Prophylaxis]

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Continuation Sheet for CIOMS report **Mfr. Control No. :E2B_05977659**

Causality

1) PATIENT HAS PASSED AWAY (Unknown cause of death (10063378), Death (10011906))
Action(s) taken with drug : Not Applicable

Seq.No. : 3
Drug : COVID-19 VACCINE(covid-19 vaccine)
Daily Dose : 1) UNK
Route of Admin : 1) Unknown
Indication for use : 1) [10084458 - COVID-19 prophylaxis]

Causality

1) PATIENT HAS PASSED AWAY (Unknown cause of death (10063378), Death (10011906))
Action(s) taken with drug : Not Applicable

Concomitant drugs (Cont...)

Seq.No. : 1
Drug : CEPHALEXIN(cephalexin)(NOT SPECIFIED)
Route of Admin : 1) Unknown
Indication for use : 1) [10070592 - Product used for unknown indication]

Causality

1) PATIENT HAS PASSED AWAY (Unknown cause of death (10063378), Death (10011906))
Action(s) taken with drug : Dosage maintained

Seq.No. : 2
Drug : AZITHROMYCIN(azithromycin)(NOT SPECIFIED)
Route of Admin : 1) Unknown
Indication for use : 1) [10070592 - Product used for unknown indication]

Causality

1) PATIENT HAS PASSED AWAY (Unknown cause of death (10063378), Death (10011906))
Action(s) taken with drug : Not Applicable

Seq.No. : 3
Drug : PREDNISONE(prednisone)(NOT SPECIFIED)
Daily Dose : 1) 50 mg (50 mg)
2) 50 mg (50 mg)
Route of Admin : 1) Unknown
2) Unknown
Indication for use : 1) [10057097 - Drug use for unknown indication]
Therapy Dates/Duration : 2) 09/27/2022 - (5 Days)

Causality

1) PATIENT HAS PASSED AWAY (Unknown cause of death (10063378), Death (10011906))
Action(s) taken with drug : Not Applicable

DRAFT

Clinical Trial Identification (Cont...)

Study identification for EudraCT:

Additional information (continuation)

Lab Result :

Test name	Test date	Test result	Normal value	Classification
10005727	[redacted]/2022	BP 190/123 unknown	unk - unk	
10033316	/ /2022	very low unstable O2 between 60 to 64 percent but %		
	[redacted]2022	1.5 l/min		
	[redacted]2022	93 %		
	[redacted]2022	1.5 l/min		

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Continuation Sheet for CIOMS report **Mfr. Control No. :E2B_05977659**

	[redacted]/2022	88 %
	[redacted]/2022	91 %
	[redacted]/2022	66 %
	[redacted]2022	50 %
		80 %
		81 %
		92 %
10037485		100 beats/min
		89 beats/min
10059938	[redacted]2022	Unknown unknown
10084356		Negative value unk - unk unknown

DRAFT

DRAFT

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Canada Vigilance AER#:	E2B_05983253 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221010 CCYYMMDD
	HC Initial Received Date:	20221010 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-656600(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220926 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220926 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2022-656600

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) OCCC MO QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-OCCC-CINT0000463 CA-MO-MOC20220927000175 CA-MODERNATX, INC.-MOD-2022-656600

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (1) E2B_05983256, (1) E2B_05983258

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)** Adult		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05983253 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02530252 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
Booster		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related

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Canada Vigilance AER#:	E2B_05983253 (0)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

I HEARD INFORMATION THAT THERE WAS A CASE IN CANADA WHERE 4 DOCTORS RECEIVED BOOSTER SHOTS AND ALL 4 DIED 2 WEEKS LATER.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a physician and describes the occurrence of DEATH (I heard information that there was a case in Canada where 4 doctors received booster shots and all 4 died 2 weeks later.) in an adult patient of an unknown gender who received mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

For mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular), the reporter did not provide any causality assessments.

No concomitant medications were reported.

It was reported that 4 doctors received Spikevax bivalent booster shots and all 4 died 2 weeks later. It was unknown that the person vaccinated received any other vaccines 4 weeks prior to the COVID-19 vaccine.

Treatment information was not provided.

This case contained information for the fourth of 4 adult patients described by the reporter.

Company comment. This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

This case was linked to CA-MODERNATX, INC.-MOD-2022-652305, CA-MODERNATX, INC.-MOD-2022-656599, CA-MODERNATX, INC.-MOD-2022-656608 (E2B Linked Report).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

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Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05983253 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_05983256 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221010 CCYYMMDD
	HC Initial Received Date:	20221010 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-656599(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220926 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220926 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2022-656599

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) OCCC MO QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-OCCC-CINT0000463 CA-MO-MOC20220927000175 CA-MODERNATX, INC.-MOD-2022-656599

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) E2B_05983253, (1) E2B_05983258, (1) E2B_05983274

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)** Adult		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05983256 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02530252 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
Booster		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

I HEARD INFORMATION THAT THERE WAS A CASE IN CANADA WHERE 4 DOCTORS RECEIVED BOOSTER SHOTS AND ALL 4 DIED 2 WEEKS LATER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a physician and describes the occurrence of DEATH (I heard information that there was a case in Canada where 4 doctors received booster shots and all 4 died 2 weeks later) in an adult patient of an unknown gender who received mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

For mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular), the reporter did not provide any causality assessments.

Concomitant medication was not reported.
Treatment details were not reported.
It was unknown that the person vaccinated received any other vaccines 4 weeks prior to the COVID-19 vaccine.

This case contained information for the second of 4 adult patients described by the reporter.

Company comment. This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

This case was linked to CA-MODERNATX, INC.-MOD-2022-652305, CA-MODERNATX, INC.-MOD-2022-656608, CA-MODERNATX, INC.-MOD-2022-656600 (E2B Linked Report).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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Canada Vigilance AER#:	E2B_05983256 (0)	Page#5

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date (B.1.8e)**
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date (B.1.10.8e)**
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**

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Canada Vigilance AER#:	E2B_05983256 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Canada Vigilance AER#:	E2B_05983258 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221010 CCYYMMDD
	HC Initial Received Date:	20221010 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-652305(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220926 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220926 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2022-652305

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) OCCC MO CRS QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-OCCC-CINT0000463 CA-MO-MOC20220927000175 MOC20220927000175 CA-MODERNATX, INC.-MOD-2022-652305

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05983256, (2) , (2) E2B_05983253, (1) E2B_05983274

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)** Adult		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05983258 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02530252 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
Booster		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

I HEARD INFORMATION THAT THERE WAS A CASE IN CANADA WHERE 4 DOCTORS RECEIVED BOOSTER SHOTS AND ALL 4 DIED 2 WEEKS LATER.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a physician and describes the occurrence of DEATH (I heard information that there was a case in Canada where 4 doctors received booster shots and all 4 died 2 weeks later.) in an adult patient of an unknown gender who received mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

For mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular), the reporter did not provide any causality assessments.

It was reported that 4 doctors received booster shots and all 4 died 2 weeks later.

Concomitant medications were not reported.

No treatment information was provided by the reporter.

This case contained information for the first of 4 adult patients described by the reporter.

Company comment. This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

This case was linked to CA-MODERNATX, INC.-MOD-2022-656599, CA-MODERNATX, INC.-MOD-2022-656608, CA-MODERNATX, INC.-MOD-2022-656600 (E2B Linked Report).

Most recent FOLLOW-UP information incorporated above includes:
On 26-Sep-2022: Upon internal review on 10-Oct-2022, significant correction was performed: This case was updated from invalid to valid and narrative was updated accordingly

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_05983258 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Canada Vigilance AER#:	E2B_05983274 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20221010 CCYYMMDD	
	HC Initial Received Date: 20221010 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-656608(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20220926 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220926 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2022-656608

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) OCCC MO QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-OCCC-CINT0000463 CA-MO-MOC20220927000175 CA-MODERNATX, INC.-MOD-2022-656608

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_05983258, (2) E2B_05983256

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)** Adult		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_05983274 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02530252 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
Booster dose		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

I HEARD INFORMATION THAT THERE WAS A CASE IN CANADA WHERE 4 DOCTORS RECEIVED BOOSTER SHOTS AND ALL 4 DIED 2 WEEKS LATER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a physician and describes the occurrence of DEATH (I heard information that there was a case in Canada where 4 doctors received booster shots and all 4 died 2 weeks later) in an adult patient of an unknown gender who received mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

For mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Intramuscular), the reporter did not provide any causality assessments.

No concomitant medications were reported.

It was reported that 4 doctors received Spikevax bivalent booster shots and all 4 died 2 weeks later. The vaccinator did not authorize Moderna to communicate with health care professional. It was unknown that the person vaccinated received any other vaccines 4 weeks prior to the COVID-19 vaccine.

No treatment medications were reported.

This case contained information for the Third adult patient out of 4 patients described by the reporter.

Company comment. This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

This case was linked to CA-MODERNATX, INC.-MOD-2022-652305, CA-MODERNATX, INC.-MOD-2022-656599 (E2B Linked Report).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This fatal spontaneous case concerns an adult patient (of an unknown gender and unknown exact age) with no reported medical history, who received a booster dose of mRNA - 1273.214 vaccine and experienced the unexpected serious event of death. Latency cannot be properly assessed since event's date and vaccination date were not provided. However, the report stated that four patients (doctors) received a booster shot and died 2 weeks later. The cause of death was not specified. It is unknown whether an autopsy was performed. No further clinical information has been provided for medical review. The benefit-risk relationship of mRNA-1273.214 is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

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Canada Vigilance AER#:	E2B_05983274 (0)	Page#5

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Canada Vigilance AER#:	E2B_05995344 (5)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230315 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202201223011(6)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20221011 CCYYMMDD	20230310 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202201223011

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_05611972 A202204950 CA-PFIZER INC-202201223011

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female	166 Centimeter	56 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			63 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Abdominal discomfort
26.0	Blood pressure decreased
26.0	Blood urine present
26.0	Cancer fatigue
26.0	Chest wall cyst
26.0	Chromaturia
26.0	Gastrooesophageal reflux disease
26.0	Haemoglobin decreased
26.0	Herpes zoster
26.0	Jaundice
26.0	Joint swelling
26.0	Laboratory test abnormal
26.0	Lethargy
26.0	Melanocytic naevus
26.0	Nausea
26.0	Off label use
26.0	Ovarian cancer metastatic
26.0	Procedural haemorrhage

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)
Suspect	COVID-19 VACCINE
Active Substance names (B.4.k.2.2)	
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)
Canada	
Holder and authorization/application no. of drug (B.4.k.4)	

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Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Abdominal discomfort	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Abdominal mass	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood pressure decreased	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood urine present	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cancer fatigue	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chest wall cyst	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chromaturia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastrointestinal cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gastrooesophageal reflux disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Haemoglobin decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Herpes zoster	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hypersomnia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaundice	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Laboratory test abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lethargy	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Mass	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Melanocytic naevus	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Neoplasm malignant	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label use	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian cancer metastatic	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ovarian mass	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Procedural haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Skin neoplasm excision	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Uterine mass	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SOLIRIS SINGLE USE, 300 MG/30ML	
Active Substance names (B.4.k.2.2)		
eculizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02322285 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
900 Milligram		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Paroxysmal nocturnal haemoglobinuria
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	IMOVANE	
Active Substance names (B.4.k.2.2)		
zopiclone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
5 Milligram		
Dosage text (B.4.k.6)		
5 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ERGOCALCIFEROL	
Active Substance names (B.4.k.2.2)		
ergocalciferol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2000 IU (International Unit)		
Dosage text (B.4.k.6)		
2000 iU		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL DISCOMFORT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Abdominal discomfort		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Abdominal discomfort		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD PRESSURE DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Blood pressure decreased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Blood pressure decreased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD URINE PRESENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Blood urine present
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Blood urine present

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CANCER FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cancer fatigue
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cancer fatigue

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHEST WALL CYST

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chest wall cyst
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Chest wall cyst

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHROMATURIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chromaturia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Chromaturia

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GASTROOESOPHAGEAL REFLUX DISEASE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Gastrooesophageal reflux disease
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Gastrooesophageal reflux disease

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAEMOGLOBIN DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Haemoglobin decreased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Haemoglobin decreased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HERPES ZOSTER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Herpes zoster
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Herpes zoster

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

JAUNDICE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Jaundice
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Jaundice

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

JOINT SWELLING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Joint swelling		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Joint swelling		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LABORATORY TEST ABNORMAL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Laboratory test abnormal		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Laboratory test abnormal		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LETHARGY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lethargy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Lethargy		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MELANOCYTIC NAEVUS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Melanocytic naevus		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Melanocytic naevus		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nausea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Nausea		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

OFF LABEL USE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Off label use		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Off label use		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OVARIAN CANCER METASTATIC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Ovarian cancer metastatic		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Ovarian cancer metastatic		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PROCEDURAL HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Procedural haemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Procedural haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OVARIAN CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Ovarian cancer		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Ovarian cancer		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NEOPLASM MALIGNANT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Neoplasm malignant		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Neoplasm malignant		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MASS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Mass
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Mass

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OVARIAN MASS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Ovarian mass
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Ovarian mass

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SKIN NEOPLASM EXCISION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Skin neoplasm excision
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Skin neoplasm excision

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UTERINE MASS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Uterine mass
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Uterine mass

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL MASS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Abdominal mass

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MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Abdominal mass		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GASTROINTESTINAL CANCER METASTATIC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Gastrointestinal cancer metastatic		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Gastrointestinal cancer metastatic		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HYPERSOMNIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hypersomnia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hypersomnia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Summary (B.5)

Case narrative (B.5.1)

NON-INTERVENTIONAL POST-MARKETING STUDY - PROTOCOL TITLE NOT AVAILABLE

This is a non-interventional study report received from contactable reporters (Consumer or other non HCP and Other HCP) from Regulatory Authority. Regulatory number: E2B_05611972 (Health Canada). Other Case identifier: A202204950 (Unknown MAH).

A 63-year-old female patient received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) intramuscular for COVID-19 immunisation; eculizumab (SOLIRIS), first regimen details not provided (Batch/Lot number: unknown), second regimen (Batch/Lot number: unknown) for 22 days at 600 mg (1 every 1 weeks), intravenous and third regimen (Batch/Lot number: unknown) at 900 mg (1 every 2 weeks), intravenous for paroxysmal nocturnal haemoglobinuria. The patient's relevant medical history was not reported. Concomitant medications included: IMOVANE unknown; VITAMIN D [ERGOCALCIFEROL] unknown.
The following information was reported: ABDOMINAL DISCOMFORT (death, hospitalization, medically significant), outcome "fatal"; BLOOD PRESSURE DECREASED (death, hospitalization, medically significant), outcome "fatal"; BLOOD URINE PRESENT (death, hospitalization, medically significant), outcome "fatal"; CANCER FATIGUE (death, hospitalization, medically significant), outcome "fatal"; CHEST WALL CYST (death, hospitalization, medically significant), outcome "fatal"; CHROMATURIA (death, hospitalization, medically significant), outcome "fatal"; GASTROOESOPHAGEAL REFLUX DISEASE (death, hospitalization, medically significant), outcome "fatal"; HAEMOGLOBIN DECREASED (death, hospitalization, medically significant), outcome "fatal"; HERPES ZOSTER (death, hospitalization, medically significant), outcome "fatal"; JAUNDICE (death, hospitalization, medically significant), outcome "fatal"; JOINT SWELLING (death, hospitalization, medically significant), outcome "fatal"; LABORATORY TEST ABNORMAL (death, hospitalization, medically significant), outcome "fatal"; LETHARGY (death, hospitalization, medically significant), outcome "fatal"; MELANOCYTIC NAEVUS (death, hospitalization, medically significant), outcome "fatal"; NAUSEA (death, hospitalization, medically significant), outcome "fatal"; OFF LABEL USE (death, hospitalization, medically significant), outcome "fatal"; OVARIAN CANCER METASTATIC (death, hospitalization, medically significant), outcome "fatal"; PROCEDURAL HAEMORRHAGE (death, hospitalization, medically significant), outcome "fatal"; OVARIAN CANCER (hospitalization, medically significant), outcome "not recovered"; NEOPLASM MALIGNANT (hospitalization, medically significant), outcome "not recovered"; MASS (hospitalization, medically significant), outcome "not recovered"; OVARIAN MASS (hospitalization, medically significant), outcome "not recovered"; SKIN NEOPLASM EXCISION (hospitalization, medically significant), outcome "not recovered"; UTERINE MASS (hospitalization, medically significant), outcome "not recovered"; ABDOMINAL MASS (hospitalization, medically significant), outcome "not recovered"; GASTROINTESTINAL CANCER METASTATIC (hospitalization, medically significant), outcome "not recovered"; HYPERSOMNIA (hospitalization, medically significant), outcome "not recovered". The patient underwent the following laboratory tests and procedures: Blood urine: present; Haemoglobin: decreased; Laboratory test: abnormal; Blood pressure measurement: decreased. The action taken for eculizumab was unknown. The patient date of death was unknown. Reported cause of death: "Abdominal discomfort",

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"Blood pressure decreased", "Blood urine present", "Cancer fatigue", "Chest wall cyst", "Chromaturia", "Gastrooesophageal reflux disease", "Haemoglobin decreased", "Herpes zoster", "Jaundice", "Joint swelling", "Laboratory test abnormal", "Lethargy", "Melanocytic naevus", "Nausea", "Off label use", "Ovarian cancer metastatic", "Procedural haemorrhage". It was not reported if an autopsy was performed.

The reporter's assessment of the causal relationship of "abdominal discomfort", "blood pressure decreased", "blood urine present", "cancer fatigue", "chest wall cyst", "chromaturia", "gastrooesophageal reflux disease", "haemoglobin decreased", "herpes zoster", "jaundice", "joint swelling", "laboratory test abnormal", "lethargy", "melanocytic naevus", "nausea", "off label use", "ovarian cancer metastatic", "procedural haemorrhage", "ovarian cancer", "neoplasm malignant", "mass", "ovarian mass", "skin neoplasm excision", "uterine mass", "abdominal mass", "gastrointestinal cancer metastatic" and "hypersomnia" with the suspect product COVID-19 Vaccine - Manufacturer Unknown was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (14Dec2022) received from the same contactable Consumer Or Other Non Health Professional as a follow up for this same patient. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number E2B_05611972. This information was initially reported to Health Canada between 01Jun2022 and 23Aug2022 from an unknown Market Authorization Holder AER# A202204950. Updated information included Events Abdominal mass, Chromaturia, Jaundice, Lethargy, Nausea and Neoplasm malignant was added.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected

Follow-up (20Jan2023) received from a new contactable Other Health Professional as a follow up for this same patient. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number E2B_05611972. This information was initially reported to Health Canada between 01Jun2022 and 26Sep2022 from an unknown Market Authorization Holder AER# A202204950. Updated information: new reporter, new events: Melanocytic naevus and Ovarian cancer.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (15Feb2023) received from the same contactable Consumer Or Other Non Health Professional as a follow up for this same patient. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number E2B_05611972. This information was initially reported to Health Canada between 01Jun2022 and 23Aug2022 from an unknown Market Authorization Holder AER# A202204950. Updated information included Events Abdominal mass, Chromaturia, Jaundice, Lethargy, Nausea and Neoplasm malignant was added.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Amendment: This follow-up report is being submitted to amend previous information: Significant PRD date in narrative from 15Feb2022 to 15Feb2023.

Follow-up (10Mar2023) received from the same contactable Other Health Professional as a follow up for this same patient. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number E2B_05611972. This information was initially reported to Health Canada between 01Jun2022 and 11Nov2022 from an unknown Market Authorization Holder AER# A202204950. Updated information included: New events (Cancer fatigue and Ovarian cancer metastatic), event details (seriousness and outcome).

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the information provided in the narrative, a causal association between the events-abdominal discomfort, blood urine present, chest wall cyst, gastrooesophageal reflux disease, haemoglobin decreased, herpes zoster, joint swelling, laboratory test abnormal, mass, off label use, ovarian mass, procedural haemorrhage, skin neoplasm excision, uterine mass, abdominal mass, chromaturia, jaundice, lethargy, nausea and "neoplasm malignant, ovarian cancer, melanocytic nevus, blood pressure decreased, gastrointestinal cancer metastatic, hypersomnia, cancer fatigue, ovarian cancer metastatic and the suspect drug cannot be completely excluded.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulattory Authorities, Ethics Committees and Investigators, as appropriate.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood pressure	decreased	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood urine	present	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Haemoglobin	decreased	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Laboratory test	abnormal	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Blood pressure decreased	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Blood urine present	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cancer fatigue	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chest wall cyst	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chromaturia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Gastrooesophageal reflux disease	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Haemoglobin decreased	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Herpes zoster	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Jaundice	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Joint swelling	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Laboratory test abnormal	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Lethargy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Melanocytic naevus	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Nausea	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Off label use	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Ovarian cancer metastatic	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Procedural haemorrhage	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Abdominal discomfort	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3) Other studies	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06004980 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221019 CCYYMMDD
	HC Initial Received Date:	20221019 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-660556(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20221011 CCYYMMDD	20221011 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2022-660556

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2022-660556

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_06004980 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Anaphylactic shock

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02530252 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Anaphylactic shock	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Anaphylactic shock	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE ANAPHYLACTIC SHOCK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Anaphylactic shock
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Anaphylactic shock

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of ANAPHYLACTIC SHOCK (Severe Anaphylactic shock) in a female patient of an unknown age who received mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) for COVID-19 prophylaxis.

Concurrent medical conditions included Emphysema, Diabetes and Chronic obstructive pulmonary disease.

On an unknown date, the patient received dose of mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (unknown route) 1 dosage form. On an unknown date, the patient experienced ANAPHYLACTIC SHOCK (Severe Anaphylactic shock) (seriousness criteria death and medically significant). The patient was treated with EPINEPHRINE (EPIPEN) at a dose of 2 doses, one in leg , one in arm. The reported cause of death was severe anaphylactic shock. It is unknown if an autopsy was performed.

Ten minute post administration of moderna vaccine later, patient had a hard time breathing and was unconscious. The nurse administered the two Epipens, one in leg and another in arm, but they could not save her.Patient died in 15 minutes.
She had no allergic reaction in past.Patient was nervous about getting the jab.

Concomitant medications were not reported.
Company comment: This is a fatal spontaneous case concerning a female patient of an unknown age, with no allergic reaction in the past, who experienced the unexpected and serious (medically significant and death) event of severe Anaphylactic shock 10 minutes after receiving an unspecified dose of mRNA-1273.214 vaccine. She had a hard time breathing and soon she was unconscious. She received 2 doses of epinephrine, one in her arm and one in her leg, but she died in 15 minutes. No details about previous doses were provided. The reported cause of death was anaphylactic shock. It is unknown if an autopsy was performed. No further clinical information was provided for medical reviewing. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This is a fatal spontaneous case concerning a female patient of an unknown age, with no allergic reaction in the past, who experienced the unexpected and serious (medically significant and death) event of severe Anaphylactic shock 10 minutes after receiving an unspecified dose of mRNA-1273.214 vaccine. She had a hard time breathing and soon she was unconscious. She received 2 doses of epinephrine, one in her arm and one in her leg, but she died in 15 minutes. No details about previous doses were provided. The reported cause of death was anaphylactic shock. It is unknown if an autopsy was performed. No further clinical information was provided for medical reviewing. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Emphysema

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Yes	

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chronic obstructive pulmonary disease	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Anaphylactic shock	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06016706 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20221025 CCYYMMDD	
	HC Initial Received Date: 20221025 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-661774(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2022[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 2022[redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) Yes		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2022-661774

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) irms QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-irms-MDCA22-02382 CA-MODERNATX, INC.-MOD-2022-661774

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 73 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMM	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	023c22a	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02530252 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
Dose 4		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2022[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED 2 DAYS AFTER RECEIVING THE BIVALENT VACCINE, DROPPED DEAD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted] CCYYMM	202[redacted] CCYYMM	1 Months
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COLLAPSED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fall		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fall		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted] CCYYMM	202[redacted] CCYYMM	1 Months
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	No adverse event		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	No adverse event		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	No adverse event
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	No adverse event

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a pharmacist and describes the occurrence of DEATH (died 2 days after receiving the bivalent vaccine, dropped dead) in a 73-year-old male patient who received mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (batch no. 023c22a) for COVID-19 prophylaxis. The occurrence of additional non-serious events is detailed below.

Previously administered products included for Drug use for unknown indication: COVID-19 vaccine (Unknown dose 1) on 20-Apr-2021, COVID-19 vaccine (Unknown dose 2) on 24-Jun-2021 and COVID-19 vaccine (Unknown dose 3) on 05-Dec-2021.
Past adverse reactions to the above products included No adverse event with COVID-19 vaccine, COVID-19 vaccine and COVID-19 vaccine.

On [redacted]022, the patient received fourth dose of mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (unknown route) 1 dosage form. In [redacted] 2022, the patient experienced DEATH (died 2 days after receiving the bivalent vaccine, dropped dead) (seriousness criteria death and medically significant) and FALL (collapsed). In [redacted] 2022, FALL (collapsed) outcome was unknown. The patient died in [redacted] 2022. The cause of death was not reported. An autopsy was performed, but no results were provided.

For mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Unknown), the reporter did not provide any causality assessments.

No concomitant medications were reported.

Patient was fine for 2 days after vaccination, did not have any side effects, he was doing well and suddenly while he was watching tv he collapsed and dropped dead. His wife came in today and she was telling that it was because of the vaccine. The autopsy is being done in the hospital and the report is not yet out. Patient's wife said that the patient died 2 days after receiving the bivalent vaccine.

No treatment medications were reported.

Company Comment: This is a Spontaneous case reported by a pharmacist, concerning a 73-year-old male patient, with no medical history reported, who experienced the unexpected event of Death, which occurred 2 days after mRNA-1273.214 vaccine, administered as fourth dose within COVID-19 vaccination schedule. It was reported that patient was doing well and suddenly while he was watching tv, he collapsed and dropped dead. The cause of death was not reported. An autopsy was performed, but not results were provided yet. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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This is a Spontaneous case reported by a pharmacist, concerning a 73-year-old male patient, with no medical history reported, who experienced the unexpected event of Death, which occurred 2 days after mRNA-1273.214 vaccine, administered as fourth dose within COVID-19 vaccination schedule. It was reported that patient was doing well and suddenly while he was watching tv, he collapsed and dropped dead. The cause of death was not reported. An autopsy was performed, but not results were provided yet. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)
20210420	
CCYYMMDD	CCYYMMDD
20210624	
CCYYMMDD	CCYYMMDD
20211205	
CCYYMMDD	CCYYMMDD

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	Drug use for unknown indication
26.0	Drug use for unknown indication
26.0	Drug use for unknown indication

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)
v.26.0	No adverse event
v.26.0	No adverse event
v.26.0	No adverse event

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Pharmacist
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221104 CCYYMMDD
	HC Initial Received Date:	20221104 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-668053(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20221102 CCYYMMDD	20221102 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2022-668053

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAF	CA-MODERNATX, INC.-MOD-2022-668053

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2) elasomeran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 1 Dosage forms		
Dosage text (B.4.k.6) 1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 2 Weeks	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Leg pain	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Leg pain	
Source of assessment (B.4.k.18.2) Non-Health care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Provided
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Thrombosis	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Thrombosis	
Source of assessment (B.4.k.18.2) Non-Health care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS THAT CAUSED HIS DEATH / HER SONS FATHER DIED IN 2021 TWO WEEKS AFTER RECEIVING THE MODERNA VACCINE.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
2 Weeks		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE HAD LEG PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Leg pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pain in extremity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
2 Weeks		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Thrombosis that caused his death / Her sons father died in 2021 two weeks after receiving the Moderna vaccine.) in a male patient of an unknown age who received mRNA-1273 (Moderna CovID-19 Vaccine) for COVID-19 prophylaxis. The occurrence of additional non-serious events is detailed below.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 (Moderna CovID-19 Vaccine) (unknown route) 1 dosage form. In 2021, the patient experienced THROMBOSIS (Thrombosis that caused his death / Her sons father died in 2021 two weeks after receiving the Moderna vaccine.) (seriousness criteria death and medically significant) and PAIN IN EXTREMITY (He had Leg pain). The patient died in 2021. The reported cause of death was Thrombosis. It is unknown if an autopsy was performed. At the time of death, PAIN IN EXTREMITY (He had Leg pain) outcome was unknown.

No concomitant information was reported.
Patient died in 2021 two weeks after receiving the Modena COVID-19 vaccine. Patient had leg pain and they found out later on that it was a type of thrombosis that caused his death.
No treatment information was reported.

Company comment:
This spontaneous case concerns a male patient of unspecified age, with no medical history reported, who experienced the Fatal, unexpected serious (Death and medically significant) AESI event of Thrombosis that occurred in the context of mRNA-1273 vaccination. Latency cannot be assessed since vaccination date was not disclosed. The event is reported as Thrombosis that caused his death / Her sons father died in 2021 two weeks after receiving the Moderna vaccine. The reported cause of death was Thrombosis. It is unknown if an autopsy was performed. No additional information regarding clinical course, diagnostic tests, concomitant medication, and treatment details. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Events seriousness was assessed as per medical judgement and available information.

Reporter did not allow further contact

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

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Sender's comments (B.5.4)

This spontaneous case concerns a male patient of unspecified age, with no medical history reported, who experienced the Fatal, unexpected serious (Death and medically significant) AESI event of Thrombosis that occurred in the context of mRNA-1273 vaccination. Latency cannot be assessed since vaccination date was not disclosed. The event is reported as Thrombosis that caused his death / Her sons father died in 2021 two weeks after receiving the Moderna vaccine. The reported cause of death was Thrombosis. It is unknown if an autopsy was performed. No additional information regarding clinical course, diagnostic tests, concomitant medication, and treatment details. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Events seriousness was assessed as per medical judgement and available information.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_06041421 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Tropiano, Stephano (HC/SC)

From: [redacted]
Sent: 2021-08-28 3:16 AM
To: Canada Vigilance [redacted](HC/SC); [redacted]
Subject: Help with reporting system

Hello i found your email on the Gov websire while looking for a way to report the death of an healthy 25 year old who went into cardiac arrest on [redacted] 2021 he passed away shortly after on the same day. He took the moderna vaccine on [redacted] 2021,he passed just 37 short days after he took his first shot. can you please direct me on how to properly report his death to the reporting system? i have searched severl times and have yet to come up with a direct link to any reporting system one link just takes me to another then another with no way to report, its very confusing. one would think that reporting should be a simple form process for something so important. please help thank you

Sent from my Galaxy

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ATIA - 19(1)

Wehbe, Rayan (HC/SC)

From: Canada Vigilance (HC/SC)
Sent: 2021-08-31 3:53 PM
To: [redacted]
Subject: Correspondence from Marketed Health Products Directorate - Adverse Reaction Number 000965271

Dear Reporter,

Thank you for submitting information to the Canada Vigilance Program (CVP). We received your email, about ARs following immunization with Moderna's COVID-19 vaccine, on August 28, 2021.

We express our deepest sympathy to you and your family for your loss and understand that this must be a difficult situation for you.

We appreciate the time you took to write about this tragic event and hope that we will address your concerns.

We have recorded your information in our database and assigned the Adverse Reaction Report (AER) number **000965271.**Please note that we will contact you about your report only if additional information is required for our surveillance activities.

What is the Canada Vigilance Program (CVP)?

The CVP is a post-market surveillance program managed by Health Canada (HC). We collect and assess reports of suspected ARs to health products. Health professionals and consumers report voluntarily, while manufacturers, distributors, and hospitals must submit reports under the *Food and Drugs Act*.

What we will do with your report

Post-market surveillance enables HC to:

- monitor the safety of marketed health products
- ensure that their benefits continue to outweigh their potential risks
- take appropriate action to minimize new risks.

Such measures may include updating the label of a health product, risk communication to inform Canadians of new ARs through safety alerts and a product recall.

Please send the following information

To help us with our surveillance activities, please send us the below follow-up information (if available):

- Vaccine lot number
- Deceased person's past medical history
- Medications and health products taken by the deceased person
- Laboratory/investigation results (if any)
- Treatments received (if any)

How to submit your follow-up information

1. Go to the online side effect reporting application.
2. Select the "follow-up" radio button.

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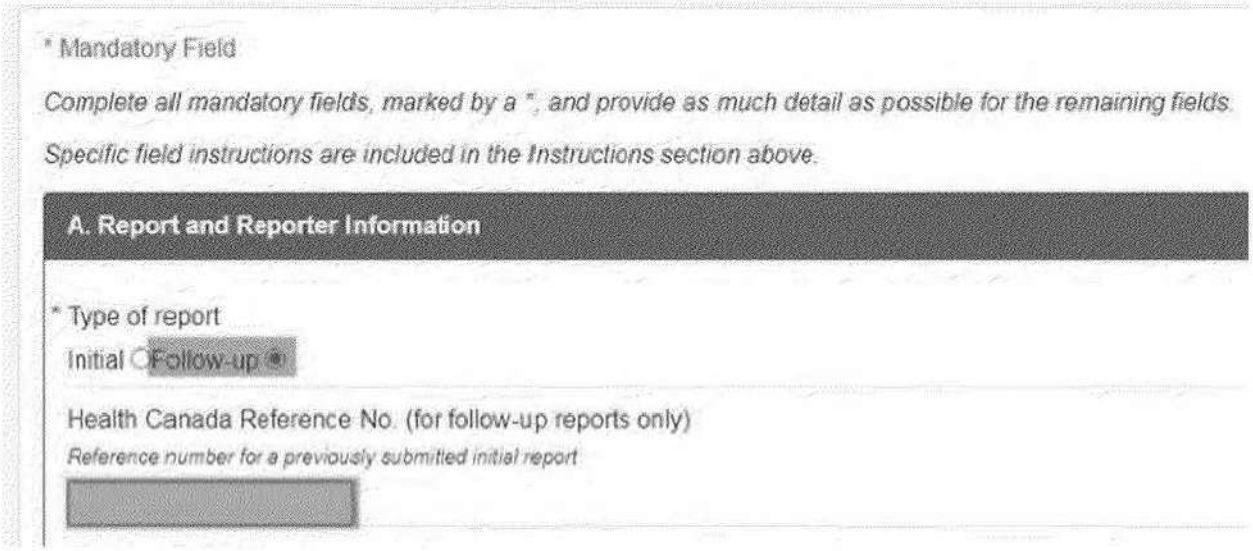
3. Enter the AER number (stated above) in the "Health Canada reference no." field as shown below:



Additional information on side effects following COVID-19 vaccine immunization

For your awareness, HC and the Public Health Agency of Canada (PHAC) share the monitoring of the safety of vaccines in Canada. To learn more, please visit the Reporting Adverse Events Following Immunization (AEFI) in Canada webpage.

HC and the PHAC collaborate closely to monitor reports of adverse events following immunization with COVID-19 vaccines in Canada through the CVP and the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). AEFI are routinely monitored. The Government of Canada publishes on a weekly basis information on AEFIs with COVID-19 vaccines. These reports do not necessarily imply that a causal relationship between the event and the vaccine has been established.

When new safety issues are confirmed, HC considers a wide variety of risk-mitigation actions. Such measures may include communicating any new risks to Canadians and healthcare providers or changing the product's recommended use.

If you witness or experience a possible reaction to a vaccine, you can report it to your health care provider. They will report possible reactions following vaccination to their local public health authority, who in turn report through their federal, provincial or territorial immunization authorities. AEFI reports are ultimately forwarded to the PHAC.

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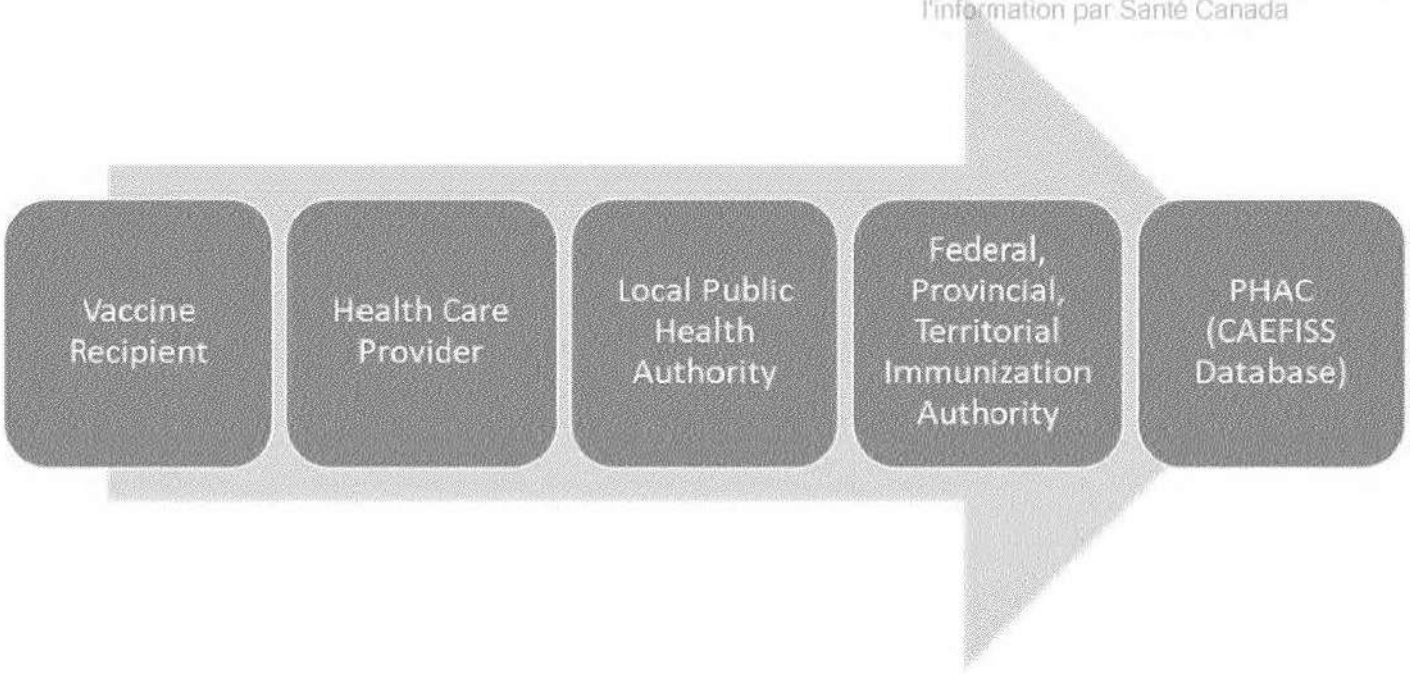

If this is not possible, consumers may report adverse reactions to vaccines directly to Health Canada through the Report a side effect application.

Since this application is not specific for vaccines, we recommend that you be as thorough as possible when completing your report.

Further information on vaccines and treatments authorized for COVID-19 can be found here: https://covid-vaccine.canada.ca/

More information

For information on health products for sale in Canada, including the Moderna vaccine, you may consult the Drug Product Database. This site allows you to search the database and read the product monographs. These provide information on contraindications, warnings, and precautions, as well as ARs associated with a particular product. You may access the Moderna vaccine product monograph in this link.

If you want to stay informed of HC's advisories, recalls, and other communication on health products, you may subscribe to MedEffect.

Once again, we would like to extend our sincere condolences and wish you the best. Please do not hesitate to contact the CVP if you need further information.

Sincerely,

Canada Vigilance Program
Health Canada, Government of Canada
canadavigilance@hc-sc.gc.ca / Tél. : 1-866-234-2345/ ATS : 1-800-465-7735

Please note that the CVP's email address has changed to canadavigilance@hc-sc.gc.ca. We encourage you to add this new email address to your safe sender list in order to ensure that you correctly receive the Program's emails.

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Programme Canada Vigilance
Santé Canada, Gouvernement du Canada
canadavigilance@hc-sc.gc.ca / Tél. : 1-866-234-2345/ ATS : 1-800-465-7735

Veuillez noter que l'adresse électronique du CVP a changé pour canadavigilance@hc-sc.gc.ca. Nous vous encourageons à ajouter cette nouvelle adresse électronique à votre liste d'expéditeurs sûrs afin de vous assurer de recevoir correctement les courriels du Programme.

Health Canada Santé Canada

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06060981 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221114 CCYYMMDD
	HC Initial Received Date:	2022 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2022121428(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2022[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 2022[redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**	
	Company number (A.1.10.2) CA-GLAXOSMITHKLINE-CA2022121428	

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) IDBQ	**Duplicate Case identifiers (A.1.11.2)** CA-GLAXOSMITHKLINE-CA2022121428

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) E2B_05238950, (2) , (2) , (2) E2B_03519675, (2) , (2) E2B_05238950, (2) , (2) , (2) E2B_03519675

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ID BIOMEDICAL CORPORATION OF QUEBEC

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 90 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06060981 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	LK8K	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg, Z, every 4 weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Eosinophilic asthma Eosinophilic asthma
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
666 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
ExpDT=30-NOV-2023		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaw movements disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaw movements disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaw movements disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaw movements disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Poor sleep	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Poor sleep	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Poor sleep	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Poor sleep	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sneezing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sneezing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sneezing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sneezing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Tiredness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Tiredness	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown

Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **FLU VACCINE**	
Active Substance names (B.4.k.2.2) influenza virus vaccine		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Prophylaxis
Start date of drug (B.4.k.12) 202[redacted] CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 28 Days	**Last period (B.4.k.13.2)** 28 Days	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cough	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaw movements disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Jaw movements disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation abnormal	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Poor sleep	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Applicable
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Poor sleep	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Applicable
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Sneezing	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Applicable
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Sneezing	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Applicable
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Applicable
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Applicable

Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **COVID-19 VACCINE**	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK ,5th dose-14-SEP-2022		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**

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Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0 26.0 26.0 26.0 26.0	Indication (B.4.k.11b) Prophylaxis Product used for unknown indication Product used for unknown indication Product used for unknown indication Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	NITROJECT	
Active Substance names (B.4.k.2.2)		
nitroglycerin		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	1 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
666 Days 28 Days	28 Days	Fatal

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHE FEELS TIRED TODAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Tiredness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Fatigue		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2022[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
584 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DID NOT SLEEP WELL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Poor sleep		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Poor quality sleep		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
583 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MILD COUGH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cough		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cough		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SNEEZING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Sneezing		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Sneezing		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

KEEPS HEARING "TEP, TEP, TEP" WHENEVER SHE MOVES HER JAW / IT IS AMPLIFIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Jaw movements disturbance		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Trismus		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHORTNESS OF BREATH ON EXERTION (SOBOE)

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Exertional dyspnea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Dyspnoea exertional

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

O2 SAT OSCILLATING BETWEEN 89 TO 90 / LOW OXYGEN SATURATION READING AT 88% PRE-SCREENING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Oxygen saturation abnormal
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oxygen saturation abnormal

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW OXYGEN SATURATION READING AT 88

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Oxygen saturation decreased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oxygen saturation decreased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

ATIA - 19(1)

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Summary (B.5)

Case narrative (B.5.1)

This case was reported by a consumer via patient support programs and described the occurrence of death in a 90-year-old female patient who received mepolizumab solution for injection in pre-filled syringe (batch number LK8K, expiry date 30th November 2023) for eosinophilic asthma.

Co-suspect products included mepolizumab pre-filled syringe device injection syringe (batch number LK8K, expiry date 30th November 2023) for eosinophilic asthma, mepolizumab solution for injection in pre-filled syringe (batch number A76R, expiry date 31st March 2025) for eosinophilic asthma, mepolizumab pre-filled syringe device injection syringe (batch number A76R, expiry date 31st March 2025) for eosinophilic asthma, Flu unspecified (Flu vaccine) for prophylaxis, COVID-19 VACCINE for prophylaxis and glyceryl trinitrate (Nitropatch) for drug use for unknown indication.

Additional subject notes included Patient had no other conditions.

On [redacted] 2021, the patient started mepolizumab (subcutaneous) 100 mg (see dose text), mepolizumab pre-filled syringe device, mepolizumab (subcutaneous) 100 mg (see dose text) and mepolizumab pre-filled syringe device. On [redacted] 2022, the patient received Flu vaccine. On an unknown date, the patient received the 1st dose of COVID-19 VACCINE. On an unknown date, the dose was an unknown dose. On an unknown date, the dose was an unknown dose. On an unknown date, the dose was an unknown dose. On an unknown date, the dose was an unknown dose. On an unknown date, the patient started Nitropatch at an unknown dose and frequency. On [redacted] 2022, 583 days after starting mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device and not applicable after receiving Flu vaccine, the patient experienced poor sleep. On [redacted] 2022, the patient experienced tiredness. On [redacted] 2022, the patient experienced death (serious criteria death and GSK medically significant). On an unknown date, the patient experienced cough, sneezing, jaw movements disturbance, exertional dyspnea, oxygen saturation abnormal and oxygen saturation decreased. On [redacted] 2022, the outcome of the death was fatal. On an unknown date, the outcome of the poor sleep, tiredness, exertional dyspnea, oxygen saturation abnormal and oxygen saturation decreased were unknown and the outcome of the cough, sneezing and jaw movements disturbance were not recovered/not resolved. The subject died on [redacted] 2022. The reported cause of death was unknown cause of death.

It was unknown if the reporter considered the death, tiredness, poor sleep, cough, sneezing, jaw movements disturbance, exertional dyspnea, oxygen saturation abnormal and oxygen saturation decreased to be related to mepolizumab, mepolizumab pre-filled syringe device, mepolizumab and mepolizumab pre-filled syringe device. It was unknown if the reporter considered the death and oxygen saturation decreased to be related to Flu vaccine. This report is made by GSK without prejudice and does not imply any admission or liability for the incident or its consequences.

Linked case(s) involving the same patient: CA2020AMR192167, CA2021223416, CA2021241535, CA2021260730, CA2022071814

GSK Receipt Date: [redacted] 2022
Reporter's Comments: This case was received via Nucala Patient Support Program (Vista). Mepolizumab used by patient was Nucala. Patient used Nucala every 4 weeks. Patient said she felt tired today [redacted] 022) as she did not sleep well last night [redacted] 2022) for unknown reason. Mild cough and sneezing was noted. Patient stated she kept hearing "tep, tep, tep" whenever she moved her jaw. She added, no pain but it was annoying more than anything else it was amplified. Patient advised to consult MD (doctor of medicine) about it. Injection was well tolerated. No further information was provided.

FU information was received on [redacted] 2022. This FU was considered as significant.
Reporter comments: Patient had shortness of breath (SOB) on exertion, Oxygen saturation oscillating between 89 to 90 percent pre-injection. Patient said she received her 5th dose of Covid-19 vaccine on [redacted] 2022 on right arm. Patient was wearing Nitropatch on left arm. Patient in good spirits. Signatory waited with writer for med delivery. Treatment administered on left abdomen. Injection well tolerated. No immediate site reaction. No voiced concerns. Patient stable upon departure. No further information provided. It was unknown if the reporter considered the tiredness, poor sleep, cough, sneezing, jaw movements disturbance, exertional dyspnea and oxygen saturation abnormal to be related Covid-19 vaccine and Nitropatch.
Summary of changes: Co-suspect Covid-19 vaccine and Nitropatch added. Event exertional dyspnea and oxygen saturation abnormal added.

Follow-up information received on [redacted] 2022.
Reporter's Comments: Patient stable when I arrived. Patient had to wait 30 minutes for her treatment as she forgot to bring out medicine from fridge. Patient stated she had blood work done, received Flu vaccine [redacted] 2022. Low Oxygen Saturation reading at 88 percent pre-screening and stabilized at 92 percent w/ 3LPM post injection. Other Vital signs stable, afebrile. Injection well tolerated. No immediate site reaction. Patient stable and asymptomatic upon my departure.
Summary of changes: lab data added, suspect product, event and narrative added.

Follow-up information received on [redacted] 2022
Reporter comment: Pre-screening, patient's granddaughter reported patient passed away in her sleep the morning of [redacted] 022. No further information provided.
Summary of changes: Patient tab updated, event tab updated, product tab updated, narrative updated.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Death is a unlisted event which is considered unrelated to GSK study drug Mepolizumab and Mepolizumab pre-filled syringe device.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Oxygen saturation	88	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Oxygen saturation	92 percent w/ 3LPM	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Oxygen saturation	between 89 to 90	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
%			Yes

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Patient had no other conditions

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date (B.1.8e)**
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)		

Study name (A.2.3.1) Mepolizumab Patient Support Program	Project No
Sponsor Study no. (A.2.3.2) Mepolizumab PSP	Observed study type (A.2.3.3) Other studies

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06063349 (7)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20230214 CCYYMMDD	
	HC Initial Received Date: 2022 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2022164678(5)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20221109 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 2023[redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-GLAXOSMITHKLINE-CA2022164678

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) 01052547635	**Duplicate Case identifiers (A.1.11.2)** CA-GLAXOSMITHKLINE-CA2022164678

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

NAH - GLAXOSMITHKLINE

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 76 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06063349 (7)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2023[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Chronic obstructive pulmonary disease
26.0	Lung cancer

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg, Z (every 4 weeks)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Eosinophilic asthma Eosinophilic asthma
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Primary dosage regimen		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bronchitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bronchitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bronchitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bronchitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chronic obstructive pulmonary disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chronic obstructive pulmonary disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chronic obstructive pulmonary disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chronic obstructive pulmonary disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus infection	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus test positive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus test positive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus test positive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus test positive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased shortness of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased shortness of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Increased shortness of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased shortness of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Rhonchi	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	No

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MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Rhonchi	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** No
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Rhonchi	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Rhonchi	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** No
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** No
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Tiredness	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown

Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **INFLUENZA VACCINES**	
Active Substance names (B.4.k.2.2) influenza virus vaccine		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**

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Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2022[redacted] CCYYMM		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bronchitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bronchitis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chronic obstructive pulmonary disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chronic obstructive pulmonary disease	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coronavirus test positive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Coronavirus test positive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Exertional dyspnea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased shortness of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased shortness of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Not Applicable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Rhonchi	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Rhonchi	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Tiredness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Tiredness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Unknown

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2022[redacted] CCYYMM		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ZENHALE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2 Dosage forms,2 every 1 (Days)		
Dosage text (B.4.k.6)		
2 puff(s), bid 200/5mcg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Inhalation	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** TIOTROPIUM BROMIDE MONOHYDRATE	
Active Substance names (B.4.k.2.2) tiotropium bromide monohydrate		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 2 Dosage forms,1 every 1 (Days)		
Dosage text (B.4.k.6) 2 puff(s), qd 2.5 mcg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Inhalation	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VENTOLIN	
Active Substance names (B.4.k.2.2)		
salbutamol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2 Dosage forms		
Dosage text (B.4.k.6)		
2 puff(s), Z, PRN (as necesary) 100 mcg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Inhalation	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT PASSED AWAY / COMPLICATIONS OF HER LUNG CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lung cancer		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Lung neoplasm malignant		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
		2023[redacted] CCYYMMDD	
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT PASSED AWAY / COMPLICATIONS OF HER COPD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chronic obstructive pulmonary disease
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Chronic obstructive pulmonary disease

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
		2023[redacted] CCYYMMDD	

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAS A LUNG INFECTION/HAVING A LUNG INFECTION.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Lung infection
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FEELING TIRED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Tiredness
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Fatigue

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHORTNESS OF BREATH /OUTCOME OF PROBLEM WORSENED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Increased shortness of breath
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Dyspnoea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RHONCHI ON EXPIRATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Rhonchi
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Rhonchi

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRONCHITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Bronchitis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Bronchitis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

TESTED COVID+

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Coronavirus test positive
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Coronavirus test positive

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
38 Days		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

TESTED COVID+

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Coronavirus infection
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Coronavirus infection

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
38 Days		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

STILL FEELS SOB ON EXERTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Exertional dyspnea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Dyspnoea exertional

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

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Summary (B.5)

Case narrative (B.5.1)

This case was reported by a consumer via patient support programs and described the occurrence of lung cancer in a 76-year-old female patient who received mepolizumab solution for injection in pre-filled pen for eosinophilic asthma.

Co-suspect products included mepolizumab autoinjector device administration system (batch number Unk, expiry date unknown) for eosinophilic asthma, mepolizumab solution for injection in pre-filled pen (batch number EC7Y, expiry date 1st February 2025) for eosinophilic asthma, mepolizumab autoinjector device administration system (batch number EC7Y, expiry date 1st February 2025) for eosinophilic asthma, Flu Seasonal QIV Quebec (Canadian influenza vaccine Quadrivalent 2022-2023 season) for prophylaxis and COVID-19 VACCINE (COVID VACCINE) for covid-19 prophylaxis.

Additional subject notes included No patient history was reported. Concomitant products included formoterol fumarate, mometasone furoate (Zenhale), tiotropium bromide (Spiriva Respimat) and salbutamol (Ventolin).

On [redacted]2022, the patient started mepolizumab (subcutaneous) 100 mg (see dose text), mepolizumab autoinjector device, mepolizumab (subcutaneous) 100 mg (see dose text) and mepolizumab autoinjector device. In [redacted]2022, the patient received Canadian influenza vaccine Quadrivalent 2022-2023 season and COVID VACCINE. On [redacted]2022, 38 days after starting mepolizumab, mepolizumab autoinjector device, mepolizumab and mepolizumab autoinjector device and less than a week after receiving Canadian influenza vaccine Quadrivalent 2022-2023 season, the patient experienced coronavirus test positive and coronavirus infection. On an unknown date, the patient experienced lung cancer (serious criteria death and GSK medically significant), chronic obstructive pulmonary disease (serious criteria death), lung infection (serious criteria hospitalization and GSK medically significant), tiredness (serious criteria hospitalization), increased shortness of breath (serious criteria hospitalization), rhonchi (serious criteria hospitalization), bronchitis and exertional dyspnea. The subject was treated with antibiotics nos (Antibiotics (Brand Names Not Known)), ciprofloxacin, meropenem and prednisone. On [redacted]2023, the outcome of the lung cancer and chronic obstructive pulmonary disease were fatal. On an unknown date, the outcome of the lung infection, tiredness, increased shortness of breath, rhonchi and exertional dyspnea were not recovered/not resolved and the outcome of the coronavirus test positive, coronavirus infection and bronchitis were unknown. The subject died on [redacted]2023. The reported cause of death was chronic obstructive pulmonary disease and lung cancer.

It was unknown if the reporter considered the lung cancer, chronic obstructive pulmonary disease, tiredness, increased shortness of breath, rhonchi, bronchitis, coronavirus test positive, coronavirus infection and exertional dyspnea to be related to mepolizumab, mepolizumab autoinjector device, mepolizumab and mepolizumab autoinjector device. The reporter considered the lung infection to be unrelated to mepolizumab, mepolizumab autoinjector device, mepolizumab and mepolizumab autoinjector device. It was unknown if the reporter considered the lung cancer, chronic obstructive pulmonary disease, tiredness, increased shortness of breath, rhonchi, coronavirus test positive, coronavirus infection and exertional dyspnea to be related to Canadian influenza vaccine Quadrivalent 2022-2023 season. This report is made by GSK without prejudice and does not imply any admission or liability for the incident or its consequences.

Additional Information:
GSK Receipt date: [redacted]2022
Reporter's Comment: This report was received from consumer via Nucala Patient Support Program (Vista). Mepolizumab the patient received was Nucala and its frequency was every 4 weeks. On [redacted]2022 patient called to inform that she currently had a lung infection and was taking antibiotics. No further information was provided.

Follow-up information received on [redacted]2022
Reporter's Comments: This case was received from Nucala patient support program (Vista). The Mepolizumab took by patient was Nucala (every 4 weeks). Patient was on Ciprofloxacin for 7 days for bronchitis. Did not consent to contact. No further information provided.
Summary of Changes: Suspect product, event, treatment medication added

Follow up information was received on [redacted]2022
Reporters comment-Patient mentioned having a lung infection. Feeling tired, more Shortness of breath, rhonchi on expiration. Spent some time in the hospital. Is on Meropenem 2g IV for 7days (until [redacted] & Prednisone. Received her flu plus COVID shot last week of [redacted] Tested COVID positive on [redacted] Saw her MD yesterday [redacted] and will see him again Monday [redacted]
TTO of coronavirus test positive and coronavirus infection was less than a week with Covid-19 vaccine, TTO of tiredness, increased shortness of breath and rhonchi was less than a month with Flu vaccine and Covid-19 vaccine. It was unknown if the reporter considered the tiredness, increased shortness of breath, rhonchi, coronavirus test positive and coronavirus infection to be related to Covid-19 vaccine.
Summary of changes-event added, co suspect added , treatment medication added, lab data added.

Follow up information was received on [redacted]2023
Reporters comment: Post infusion report Patient calm. Mentioned there had not been any changes in her health status. Still felt SOB (Shortness of breath) on exertion. Had a follow up appointment with her doctor this week. Husband present. Patient was stable upon departure. It was unknown if the reporter considered the exertional dyspnea to be related to COVID-19 VACCINE .
Summary of changes: event added.

Follow-up information received on [redacted]2023
Reporter comments: Nurse was able to get a hold of the patient's husband who unfortunately notified that, the patient passed away the day before morning. He mentioned that, it was due to complications of her lung cancer and COPD, but was unable to give more details. It was unknown if the reporter considered the lung cancer, chronic obstructive pulmonary disease to be related to COVID-19 vaccine.
Summary of Changes: Product tab, event tab and narrative updated.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Lung neoplasm malignant, Chronic obstructive pulmonary disease , Fatigue, ronchi and dyspnoea are unlisted events which are considered unrelated to GSK study drug Mepolizumab and Mepolizumab autoinjector device.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
2024[redacted] CCYYMMDD	Coronavirus test	Coronavirus test positive

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
unknown			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chronic obstructive pulmonary disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Lung cancer	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

No patient history was reported

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1) Mepolizumab Patient Support Program		Project No	
Sponsor Study no. (A.2.3.2) Mepolizumab PSP		Observed study type (A.2.3.3) Other studies	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06188877 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221226 CCYYMMDD
	HC Initial Received Date:	20221226 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-689921(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MO-MOC20221222000239

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
OCCC QMODERNAP	CA-OCCC-CINT0000752 CA-MODERNATX, INC.-MOD-2022-689921

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
	Adult		
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5) 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran davesomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	ASKU	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02532352 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Specific product reported: Yes, specific product known from information provided		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DAUGHTER DIED AFTER TAKING MODERNA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death NOS
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	1 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of DEATH (daughter died after taking Moderna) in an adult female patient who received mRNA-1273 BIVALENT .222 (SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5)) (batch no. ASKU) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 BIVALENT .222 (SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5)) (unknown route) 1 dosage form. Death occurred on [redacted] 2022 The patient died on [redacted] 2022. The cause of death was not reported. An autopsy was performed, but no results were provided.

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):
In [redacted] 022, Autopsy: Waiting on the autopsy results.

For mRNA-1273 BIVALENT .222 (SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5)) (Unknown), the reporter did not provide any causality assessments.

Concomitant product use was not provided by the reporter.

Unknown if patient received any other vaccines in the 4 weeks prior to COVID-19 vaccine.

Reporter was waiting on the autopsy results from patient.

Treatment information was not provided.
Company comment-This spontaneous case concerns an adult female, with no medical history reported, who experienced the unexpected, Fatal serious (medically significant) event of death after receiving an unspecified dose of Spikevax Bivalent .222 (Original/Omicron BA.4/5) vaccine. Latency cannot be assessed since exact vaccination date was not disclosed. Death occurred on [redacted] 022. An autopsy was performed reports not available. The reported cause of death was unknown. It was reported that 'daughter died after taking Moderna/waiting on the autopsy results from my daughter'. No further clinical information was available for review. The benefit-risk relationship of Spikevax Bivalent .222 (Original/Omicron BA.4/5) vaccine is not affected by this report.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This spontaneous case concerns an adult female, with no medical history reported, who experienced the unexpected, Fatal serious (medically significant) event of death after receiving an unspecified dose of Spikevax Bivalent .222 (Original/Omicron BA.4/5) vaccine. Latency cannot be assessed since exact vaccination date was not disclosed. Death occurred on [redacted] 2022. An autopsy was performed reports not available. The reported cause of death was unknown. It was reported that 'daughter died after taking Moderna/waiting on the autopsy results from my daughter'. No further clinical information was available for review. The benefit-risk relationship of Spikevax Bivalent .222 (Original/Omicron BA.4/5) vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
2022[redacted] CCYYMM	Autopsy	

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes

Results of tests and procedures (B.3.2)

Autopsy [redacted] 2022;;Waiting on the autopsy results

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Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_06188877 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Canada Vigilance AER#:	E2B_06190743 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20221227 CCYYMMDD	
	HC Initial Received Date: 20221227 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2022-690190(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20221221 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20221221 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) Yes		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MO-MOC20221222000243

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) OCCC CHS QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-OCCC-CINT0000753 MOC20221222000243 CA-MODERNATX, INC.-MOD-2022-690190

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

NAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_06190743 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran imelasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02530252 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Yes, specific product known from information provided.		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNKNOWN CAUSE OF DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Unknown cause of death) in a female patient of an unknown age who received mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. An autopsy was performed, but no results were provided.

The action taken with mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Unknown) was unknown.

For mRNA-1273 BIVALENT (SPIKEVAX BIVALENT) (Unknown), the reporter did not provide any causality assessments.

No concomitant medication provided.
No treatment medication provided.

Company comment:
This spontaneous case concerns a female patient of unknown age, with no medical history reported, who experienced the fatal unexpected serious event of Death that occurred unknown days after receiving a dose of mRNA-1273 bivalent BA.1 vaccine in covid-19 vaccination series. The reported cause of death and date of death was unknown. Autopsy was performed, however the report was not available. No further information on patients' medical history, circumstances leading to death, exact cause of death, concomitant medications, additional vaccination details were provided. The benefit-risk relationship of mRNA-1273 bivalent BA.1 vaccine is not affected by this report.

Reporter did not allow further contact

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This spontaneous case concerns a female patient of unknown age, with no medical history reported, who experienced the fatal unexpected serious event of Death that occurred unknown days after receiving a dose of mRNA-1273 bivalent BA.1 vaccine in covid-19 vaccination series. The reported cause of death and date of death was unknown. Autopsy was performed, however the report was not available. No further information on patients' medical history, circumstances leading to death, exact cause of death, concomitant medications, additional vaccination details were provided. The benefit-risk relationship of mRNA-1273 bivalent BA.1 vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Canada Vigilance AER#:	E2B_06190743 (0)	

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06227099 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230113 CCYYMMDD
	HC Initial Received Date:	20230113 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2023-695946(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230110 CCYYMMDD	20230110 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-MODERNATX, INC.-MOD-2023-695946

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
QMODERNAP	CA-MODERNATX, INC.-MOD-2023-695946

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			72 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_06227099 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Canada Vigilance AER#:	E2B_06227099 (0)	Page#3

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2) elasomeran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 1 Dosage forms		
Dosage text (B.4.k.6) Dose 1		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19) Specific product reported: Yes, specific product known from information provided.		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Short of breath	
Source of assessment (B.4.k.18.2) Health Care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Provided
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Short of breath	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Sudden death	
Source of assessment (B.4.k.18.2) Health Care professional	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Provided
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Sudden death	
Source of assessment (B.4.k.18.2) MAH	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUDDEN DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Sudden death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Sudden death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHORT OF BREATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Short of breath		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) in a 72-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 prophylaxis. The occurrence of additional non-serious events is detailed below.

Concurrent medical conditions included COPD.

On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced SUDDEN DEATH (Sudden death) (seriousness criteria death and medically significant) and DYSPNOEA (Short of breath). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, DYSPNOEA (Short of breath) outcome was unknown.

For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.

Concomitant and treatment medications were not reported.

One presumed vaccine induced sudden death (in a 72-year-old patient With COPD). This patient complained of being short of breath continually after receiving the vaccine and died very suddenly and unexpectedly on day 24 after the vaccine. Patient had no history of cardiovascular disease.

Company comment: This fatal regulatory authority case concerns a 72-year-old male patient, with chronic obstructive pulmonary disease but no history of cardiovascular disease, who experienced dyspnoea continually after receiving the first dose of mRNA-1273 vaccine and suddenly died (unexpected and serious due to medically significant and death) 24 days after vaccination. The events were reported with no onset date and the vaccination dates were not reported either; hence, latency could not be properly assessed. The reported cause of death was not reported. It is unknown if an autopsy was performed. No further clinical information was available for medical review. Patient's chronic obstructive pulmonary disease could be a confounder for dyspnoea and could be a risk factor for his sudden death. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

This case was linked to US-MODERNATX, INC.-MOD-2023-695829, CA-MODERNATX, INC.-MOD-2023-695941 (E2B Linked Report).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	COPD	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06234572 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230327 CCYYMMDD
	HC Initial Received Date:	2023 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202300018478(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230114 CCYYMMDD	20230326 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202300018478

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202300018478

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			70 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 72 Days	**Last period (B.4.k.13.2)** 72 Days	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06234572 (2)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
72 Days	72 Days	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP).

A 70-year-old male patient received BNT162b2 (COMIRNATY), on [redacted]021 as dose 2, single (Batch/Lot number: unknown) at the age of 70 years for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Pfizer (Dose Number: 1; Lot number unknown), for COVID-19 immunization.
The following information was reported: DEATH (death, hospitalization, medically significant) with onset [redacted]2021, outcome "fatal". The patient was hospitalized for death (hospitalization duration: 21 day(s)). The patient underwent the following laboratory tests and procedures: SARS-CoV-2 test: unknown result. Therapeutic measures were taken as a result of death. The patient date of death was [redacted]2021. The reported cause of death was unknown. It was not reported if an autopsy was performed.

Clinical course: No known drug allergy. Upon FU on 07Feb2023 Reporter clarified name of reporter/patient. (Confirmed that his brother who passed away was PRIVACY).

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.

Follow-up (07Feb2023): This is a spontaneous follow-up report received from a contactable consumer (patient's brother). Updated information included: reporter tabl (last name), patient's name and additional information added.
Follow-up (26Mar2023): Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
	COVID-19 PCR test	unknown result

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_06234572 (2)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a) PFIZER BIONTECH COVID-19 VACCINE	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	Indication (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06251854 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230124 CCYYMMDD
	HC Initial Received Date:	20230124 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202300030873(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230120 CCYYMMDD	20230120 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202300030873

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_05742627 CA2022103680 CA-PFIZER INC-202300030873

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			77 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Dyspnoea
26.0	Hypotension
26.0	Loss of consciousness

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Dyspnoea	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Hypotension	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Loss of consciousness	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Asthma
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	FLOVENT	
Active Substance names (B.4.k.2.2)		
fluticasone propionate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK, 2x/day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	GLYCOPYRRONIUM BROMIDE;INDACATEROL MALEATE	
Active Substance names (B.4.k.2.2)		
GLYCOPYRRONIUM BROMIDE INDACATEROL MALEATE		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK, 1x/day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PREDNISONE	
Active Substance names (B.4.k.2.2)		
prednisone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VENTOLIN [SALBUTAMOL]	
Active Substance names (B.4.k.2.2) SALBUTAMOL		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK, 1x/day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSPNOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dyspnoea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HYPOTENSION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hypotension		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hypotension		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOSS OF CONSCIOUSNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Loss of consciousness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Loss of consciousness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

NON-INTERVENTIONAL POST-MARKETING STUDY - PROTOCOL TITLE NOT AVAILABLE

This is a non-interventional study report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: E2B_05742627 (Health Canada). Other Case identifier(s): CA2022103680 (Unknown MAH). (Linked or duplicate Regulatory number: E2B_03837154, E2B_02776365, E2B_01954979, E2B_04638235).

A 77-year-old female patient received COVID-19 Vaccine - Manufacturer Unknown, as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation; mepolizumab (MEPOLIZUMAB), (Batch/Lot number: unknown) at 100 mg, subcutaneous for asthma. The patient's relevant medical history was not reported. Concomitant medication (s) included: FLOVENT unknown; GLYCOPYRRONIUM BROMIDE;INDACATEROL MALEATE unknown; PREDNISONE unknown; VENTOLIN [SALBUTAMOL] unknown.
The following information was reported: DEATH (death, hospitalization, medically significant), outcome "fatal"; DYSPNOEA (death, hospitalization, medically significant), outcome "fatal"; HYPOTENSION (death, hospitalization, medically significant), outcome "fatal"; LOSS OF CONSCIOUSNESS (death, hospitalization, medically significant), outcome "fatal". The action taken for mepolizumab was unknown. The date and cause of death for the patient were unknown.

The reporter's assessment of the causal relationship of "death", "dyspnoea", "hypotension" and "loss of consciousness" with the suspect product(s) COVID-19 Vaccine - Manufacturer Unknown was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the available information and close temporal association, a possible causal relationship cannot be excluded between the suspect vaccine BNT162b2 and the reported events death, hypotension, dyspnea, loss of consciousness.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypotension	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Loss of consciousness	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3) Other studies	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06263148 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230209 CCYYMMDD
	HC Initial Received Date:	2023 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-PV202300017827(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230126 CCYYMMDD	20230206 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-PV202300017827

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Pfizer PFIZERINC	CA-PFIZER INC-20230004148 2 CA-PFIZER INC-PV202300017827

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) 001034210

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Assisted suicide
26.0	Completed suicide

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
2021 CCYY	2021 CCYY	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Acute pain	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	

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26.0	Acute pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Assisted suicide	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Assisted suicide	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bone marrow disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bone marrow disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Faint	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Faint	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Leukemia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Leukemia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Low platelets	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Low platelets	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Nasal bleeding	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Nasal bleeding	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Protein abnormal NOS	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Protein abnormal NOS	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

[redacted]

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Assisted suicide		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Assisted suicide		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNIDENTIFIED BLOOD CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cancer		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Neoplasm malignant		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Unknown	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Leukemia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Leukaemia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE COLLAPSED FROM LOW PLATELETS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Faint		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Syncope		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAIN WAS UNBEARABLE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Acute pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW PLATELETS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Low platelets		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Platelet count decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAEMORRHAGES FROM HIS NASAL PASSAGES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nasal bleeding		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Epistaxis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

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	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) **Current reaction**

STRANGE PROTEINS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Protein abnormal NOS		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Protein total abnormal		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) **Current reaction**

EMANATING FROM HIS BONE MARROW

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Bone marrow disorder		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Bone marrow disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP) from medical information team.

A male patient received BNT162b2 (BNT162B2), in 2021 as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (Dose 1, Single, Unknown manufacturer), for Covid-19 immunization.
The following information was reported: SYNCOPE (medically significant) with onset 2021, outcome "unknown", described as "He collapsed from low platelets"; BONE MARROW DISORDER (non-serious) with onset 2021, outcome "unknown", described as "emanating from his bone marrow"; EPISTAXIS (non-serious) with onset 2021, outcome "unknown", described as "haemorrhages from his nasal passages"; PROTEIN TOTAL ABNORMAL (non-serious) with onset 2021, outcome "unknown", described as "strange proteins"; ASSISTED SUICIDE (death), outcome "fatal", described as [redacted] NEOPLASM MALIGNANT (medically significant), outcome "unknown", described as "unidentified blood cancer"; LEUKAEMIA (medically significant), outcome "unknown", described as "blood cancer"; PAIN (non-serious), outcome "unknown", described as "pain was unbearable"; PLATELET COUNT DECREASED (non-serious), outcome "unknown", described as "low platelets". The patient underwent the following laboratory tests and procedures: Platelet count: (2021) Low; Protein total abnormal: (2021) "strange proteins" filling up quickly in his blood. The patient date of death was unknown. Reported cause of death: [redacted], "He was [redacted]. It was not reported if an autopsy was performed.

Clinical course: Reporter stated that her child's grandfather who was my father-in-law had sudden adverse reactions after the second "covid-19" injection in 2021. He collapsed from low platelets, haemorrhages from his nasal passages, and was diagnosed with accelerated "unidentified blood cancer". The physician told us that he had "strange proteins" filling up quickly in his blood, emanating from his bone marrow. Before this, her child's grandfather was living happily and independently at home. He was [redacted] called [redacted] because his pain was unbearable and everyone in his professional care, said they could not help him. It was obvious that he was a victim of the worldwide experimental drug trial. My father in-law's consent form had gone missing and did not have access to his lot number in order to file an adverse reaction report on behalf of the family. The patient date of death was unknown. Reported cause of death: "He was [redacted]. It was not reported if an autopsy was performed. Reporter child's grandfather who was his father in law had sudden adverse reactions after the second "covid-19" injection in 2021. He collapsed from low platelets, haemorrhages from his nasal passages, and was diagnosed with accelerated "unidentified blood cancer". The physician told us that he had "strange proteins" filling up quickly in his blood, emanating from his bone marrow. Before this, his child's grandfather was living happily and independently at home. He was [redacted] because his pain was unbearable and everyone in his professional care, said they could not help him. It was obvious that he was a victim of the worldwide experimental drug trial. His father in law's consent form has gone missing, and he do not have access to his lot number in order to file an adverse reaction report on behalf of the family.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (06Feb2023 and 26Jan2023): This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP) from medical information team and report to notify that the case PV202300017827 and 202300041482 are duplicates. All subsequent follow-up information will be reported under manufacturer report number PV202300017827.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021 CCYY	Platelet count	Low	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021 CCYY	Protein abnormal NOS	"strange proteins" filling up quickly in his blood	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Assisted suicide	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Completed suicide	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
COVID-19 VACCINE	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230220 CCYYMMDD
	HC Initial Received Date:	2023 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202300039495(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20230126 CCYYMMDD	20230219 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202300039495

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202300039495

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			80 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 2022[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2022[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 3 Days	**Last period (B.4.k.13.2)** 3 Days	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Foggy feeling in head	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Foggy feeling in head	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart rate high	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart rate high	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Loss of control of blood sugar	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Loss of control of blood sugar	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Memory loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Memory loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FENOFIBRATE	
Active Substance names (B.4.k.2.2) fenofibrate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	INS.	
Active Substance names (B.4.k.2.2)		
insulin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 80016480 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) INSULIN LISPRO	
Active Substance names (B.4.k.2.2) insulin lispro		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) AMLODIPINE BESILATE/TELMISARTAN	
Active Substance names (B.4.k.2.2) amlodipine besylate telmisartan		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN C	
Active Substance names (B.4.k.2.2) ascorbic acid		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) CALCIUM CARBONATE/VITAMIN D3	
Active Substance names (B.4.k.2.2) calcium carbonate vitamin d3		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ZINC	
Active Substance names (B.4.k.2.2)		
zinc		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MASSIVE HEART ATTIC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
3 Days	3 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNCONTROLABLE BLOOD SUGAR

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)			
26.0	Loss of control of blood sugar			
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)			
26.0	Diabetes mellitus inadequate control			
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2022[redacted]			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
3 Days	3 Days	Unknown		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RAPID HEART RATE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)			
26.0	Heart rate high			
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)			
26.0	Heart rate increased			
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2022[redacted]			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
3 Days	3 Days	Unknown		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN FOG

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)			
26.0	Foggy feeling in head			
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)			
26.0	Brain fog			
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2022[redacted]			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
3 Days	3 Days	Unknown		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MEMORY LOSS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)			
26.0	Memory loss			
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)			
26.0	Amnesia			
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
	2022[redacted]			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
3 Days	3 Days	Unknown		

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). The reporter is the parent.

An 80-year-old female patient (not pregnant) received BNT162b2 (BNT162B2), on [redacted]2022 as dose 3 (booster), single (Batch/Lot number: unknown) at the age of 80 years, in left arm for covid-19 immunisation. The patient's relevant medical history included: "Diabetes mellitus" (unspecified if ongoing). Concomitant medication(s) included: FENOFIBRAT (ongoing); INSULIN (ongoing); LISPRO INSULIN (ongoing); TWYNSTA (ongoing); VITAMIN C ACID (ongoing); VITAMIN D 2000 (ongoing); ZINC (ongoing). Vaccination history included: pfizer covid-19 comirnaty mrna pb (Dose Number: 2, Batch/Lot No: EX0904, Location of injection: Leg Left), administration date [redacted]2021, for COVID-19 immunisation; pfizer covid-19 comirnaty mrna pb (Dose Number: 1, Batch/Lot No: EP6775, Location of injection: Arm Left), administration date: [redacted]2021, for COVID-19 immunisation.
The following information was reported: FEELING ABNORMAL (non-serious) with onset [redacted]2022, outcome "unknown", described as "Brain fog"; MYOCARDIAL INFARCTION (death, medically significant) with onset [redacted]2022, outcome "fatal", described as "Massive heart attic"; AMNESIA (non-serious) with onset [redacted]2022, outcome "unknown", described as "Memory loss"; HEART RATE INCREASED (non-serious) with onset [redacted]2022, outcome "unknown", described as "Rapid heart Rate"; DIABETES MELLITUS INADEQUATE CONTROL (medically significant) with onset [redacted]2022, outcome "unknown", described as "Uncontrolable Blood sugar". The patient underwent the following laboratory tests and procedures: Heart rate: ([redacted]2022) Rapid, notes: Rapid heart Rate. Therapeutic measures were taken as a result of myocardial infarction, diabetes mellitus inadequate control, heart rate increased, feeling abnormal, amnesia. The patient date of death was [redacted]2022. Reported cause of death: "Massive heart attic". No autopsy was performed.

Clinical course: Pfizer have permission to contact the reporter about this event. Pfizer have permission to contact your/the patient healthcare provider about this report. Facility where the most recent COVID-19 vaccine was administered was Nursing Home/Senior Living Facility. Prior to vaccination, the was patient diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Reported Event: Rapid heart Rate, Uncontrol able Blood sugar, Brain fog, Memory loss and Death. The patient received treatment for the adverse event was give insulin to bring levels down.

The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.
Follow-up (19Feb2023): Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2022[redacted] CCYYMMDD	Heart rate	Rapid	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes

Results of tests and procedures (B.3.2)

Heart rate([redacted]2022):Rapid heart Rate

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

ATIA - 19(1)

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Canada Vigilance AER#:	E2B_06263188 (1)	Page#13

Past drug therapy (B.1.8)

Drug name (B.1.8a)

PFIZER BIONTECH COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)
2021[redacted] CCYYMMDD 202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD 202[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0 26.0	**Indication** (B.1.8f.2) COVID-19 immunisation COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

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Canada Vigilance AER#:	E2B_06263188 (1)	Page#14

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06274441 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230317 CCYYMMDD
	HC Initial Received Date:	2023 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-PV202300020020(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230131 CCYYMMDD	20230313 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-PV202300020020

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-PV202300020020

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_06274441 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death NOS

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 20 Days	**Last period (B.4.k.13.2)** 20 Days	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death NOS	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death NOS	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WAS VACCINATED AND DIED 20 DAYS AFTER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death NOS
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
20 Days	20 Days	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP).

A patient (no qualifiers provided) received BNT162b2 (COMIRNATY NOS), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEATH (death), 20 days after the suspect product(s) administration, outcome "fatal", described as "was vaccinated and died 20 days after". The patient date of death was unknown. Reported cause of death: "was vaccinated and died 20 days after". It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (02Feb2023): This is a spontaneous follow-up report received from a contactable consumer. Updated information: New reporter added. Follow-up attempts are completed. No further information is expected.

Amendment: This follow-up report is being submitted to amend previously reported information: updated narrative to remove additional information regarding patient with coma (reporter with no firsthand knowledge).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death NOS	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_06274441 (2)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_06274441 (2)	Page#6

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Valenti, Anthony (HC/SC)

From: Hajdu, Patty - M.P. <Patty.Hajdu@parl.gc.ca>
Sent: 2021-[redacted] 11:31 PM
To: ministresc, hcminister (HC/SC)
Subject: Fw: Vaccine

Follow Up Flag:

Flag Status:

[redacted]

Office of the Hon. Patty Hajdu, PC
278 Confederation Building
Ottawa, ON K1A 0A6
Tel. 613-996-4792

From: [redacted]
Sent: [redacted] 2021 7:03 PM
To: health.minister@[redacted] <health.minister@[redacted]; Hajdu, Patty - M.P. <Patty.Hajdu@parl.gc.ca>
Subject: Vaccine

Dear [redacted] and Minister Hajdu,

[redacted] my partner, had his first Covid-19 vaccine with no problem. The 2nd vaccine he had, he developed big problems! He went to his doctor, Dr. [redacted] The doctor felt he needed a CPap machine and ordered it. [redacted] already had been involved with them at [redacted] hospital and they had done tests. The doctor suggested he buy one and we spent a couple of days trying to find a machine. I found a machine and we tried to order it. They contacted the [redacted] hospital and we waited for the machine. They needed the instruction on how to set it up. I contacted them and the staff at the hospital said they couldn't do it. Unfortunately, it was on friday and everyone was closed to get this machine. So we couldn't get one. I had to take him to the [redacted] hospital but it was too late on Saturday morning as he was having big problems breathing and he died Saturday night.

[redacted] died from taking the second dose of the vaccine. He was very healthy for his age till he got the vaccine. The vaccine is very dangerous! I think there should be more concern about who takes it.

I spent the last half of my nursing career doing halftime palliative care with Home Care. I had a few SARS clients then and none of them died. I am sure it has become more virulent but the way it is being treated is very concerning. [redacted] should not have died.

Sincerely,
[redacted] BN

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A2023000085

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Tropiano, Stephano (HC/SC)

From: Tsui, Zachary (HC/SC)
Sent: 2021-09-29 2:14 PM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Cc: Tran, Emily (HC/SC)
Subject: Request for AER Number
Attachments: 21-012622-444.pdf

Categories: Covid

Hi EFAX,

Would you be able to enter in this report and assign an AER number for a correspondence I'm working on. CC-ing Emily in case it gets actioned when I'm away.

Thanks,
Zachary

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A2023000085

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Canada Vigilance AER#:	E2B_06318443 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230222 CCYYMMDD
	HC Initial Received Date:	2023 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202300073283(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230118 CCYYMMDD	20230220 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202300073283

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Pfizer PFIZERINC	US-PFIZER INC-PV202300014963 CA-PFIZER INC-202300073283

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_06260017

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			77 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06318443 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 3 (BOOSTER), SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06318443 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

YOUR POISON SO-CALLED COVID VACCINES KILLED MY MOTHER / SHE DROPPED DEAD OF A HEART ATTACK / SHE DIED OF A MASSIVE HEART ATTACK SHORTLY AFTER HER 3RD DOSE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP).

A 77-year-old female patient received BNT162b2 (BNT162B2), as dose 3 (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (Primary Immunization series complete; unknown manufacturer), for COVID-19 immunization.
The following information was reported: MYOCARDIAL INFARCTION (death, medically significant) with onset [redacted]2022, outcome "fatal", described as "Your poison so-called covid vaccines killed my mother / She dropped dead of a heart attack / She died of a massive heart attack shortly after her 3rd dose". The patient date of death was [redacted]2022. Reported cause of death: "Your poison so-called covid vaccines killed my mother / She dropped dead of a heart attack". It was not reported if an autopsy was performed.

Clinical course: Reporter's mother was a healthy 77-year-old & never had heart problems in her life. She dropped dead of a massive heart attack on [redacted]2022 shortly after her third shot. She had no known heart conditions previously diagnosed.

Follow-up attempts are completed. No further information is expected.

Follow-up (20Feb2023): This is a spontaneous follow-up report received from a Consumer or other non HCP.
Updated Information: course of events and medical history details.
Follow-up attempts are completed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a) COVID-19 VACCINE	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	Indication (B.1.8f.2) COVID-19 immunization
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06322378 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230419 CCYYMMDD
	HC Initial Received Date:	2023 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202300073419(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20230216 CCYYMMDD	20230418 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202300073419

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada Unknown MAH PFIZERINC	E2B_05977659 CA2022034554 CA-PFIZER INC-202300073419

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			76 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Blood pressure increased
26.0	Chest pain
26.0	Diarrhoea
26.0	Dyspnoea exertional
26.0	Eye irritation
26.0	Heart rate increased
26.0	Oropharyngeal pain
26.0	Oxygen saturation decreased
26.0	Pneumonia
26.0	Unknown cause of death
26.0	Vaccination site pain
26.0	Wound

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	

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Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood pressure increased	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood pressure increased	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood pressure increased	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood pressure increased	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chest pain	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chest pain	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chest pain	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chest pain	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhoea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhoea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhoea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyspnoea exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyspnoea exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyspnoea exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyspnoea exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Eye irritation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Eye irritation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Eye irritation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Eye irritation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of product administration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oropharyngeal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oropharyngeal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oropharyngeal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oropharyngeal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation decreased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vaccination site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vaccination site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vaccination site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Vaccination site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Wound	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	INFLUENZA VACCINES	
Active Substance names (B.4.k.2.2)		
influenza virus vaccine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0 26.0	Asthma Asthma
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** PREDNISONE	
Active Substance names (B.4.k.2.2) prednisone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 50 Milligram		
Dosage text (B.4.k.6) 50 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)** 5 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PMS-AZITHROMYCIN	
Active Substance names (B.4.k.2.2)		
azithromycin		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
250 Milligram		
Dosage text (B.4.k.6)		
250 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CEPHALEX [CEFALEXIN]	
Active Substance names (B.4.k.2.2)		
cephalexin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
500 Milligram		
Dosage text (B.4.k.6)		
500 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD PRESSURE INCREASED

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Blood pressure increased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Blood pressure increased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHEST PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chest pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Chest pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIARRHOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Diarrhoea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Diarrhoea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSPNOEA EXERTIONAL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Dyspnoea exertional
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Dyspnoea exertional

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

EYE IRRITATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Eye irritation
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Eye irritation

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INJECTION SITE PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vaccination site pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vaccination site pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OROPHARYNGEAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Oropharyngeal pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oropharyngeal pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OXYGEN SATURATION DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Oxygen saturation decreased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oxygen saturation decreased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pneumonia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WOUND

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Wound
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Wound

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART RATE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heart rate increased

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Heart rate increased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Inappropriate schedule of product administration

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Inappropriate schedule of product administration

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

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Summary (B.5)

Case narrative (B.5.1)

This is a non-interventional study report received from contactable reporter(s) (Other HCP and Consumer or other non HCP) from Regulatory Authority. Regulatory number: E2B_05977659 (Health Canada). Other Case identifier(s): CA2022034554 (Unknown MAH).

A 76-year-old female patient received BNT162b2 (COVID-19 VACCINE NOS MANUFACTURER UNKNOWN), as dose number unknown, single (Batch/Lot number: unknown), as dose number unknown, single (Batch/Lot number: unknown), as dose number unknown, single (Batch/Lot number: unknown) and as dose number unknown, single (Batch/Lot number: unknown), all unknown for covid-19 immunisation; influenza vaccine (INFLUENZA VACCINE), (Batch/Lot number: unknown) for prophylaxis; mepolizumab (MEPOLIZUMAB), (Batch/Lot number: unknown) at 100 mg, subcutaneous for asthma; mepolizumab (MEPOLIZUMAB), first regimen (Batch/Lot number: unknown) at 100 mg and second regimen (Batch/Lot number: unknown) at 100 mg, all subcutaneous for asthma. The patient's relevant medical history was not reported. Concomitant medication(s) included: PREDNISONE unknown; AZITHROMYCIN unknown; CEPHALEX [CEFALEXIN] unknown. The following information was reported: DEATH (death, hospitalization, medically significant), outcome "fatal"; BLOOD PRESSURE INCREASED (death, hospitalization, medically significant), outcome "fatal"; CHEST PAIN (death, hospitalization, medically significant), outcome "fatal"; DIARRHOEA (death, hospitalization, medically significant), outcome "fatal"; DYSPNOEA EXERTIONAL (death, hospitalization, medically significant), outcome "fatal"; EYE IRRITATION (death, hospitalization, medically significant), outcome "fatal"; VACCINATION SITE PAIN (death, hospitalization, medically significant), outcome "fatal", described as "Injection site pain"; OROPHARYNGEAL PAIN (death, hospitalization, medically significant), outcome "fatal"; OXYGEN SATURATION DECREASED (death, hospitalization, medically significant), outcome "fatal"; PNEUMONIA (death, hospitalization, medically significant), outcome "fatal"; WOUND (death, hospitalization, medically significant), outcome "fatal"; HEART RATE INCREASED (death, hospitalization, medically significant), outcome "fatal"; INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (non-serious), outcome "unknown". The action taken for mepolizumab and mepolizumab was unknown. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

The reporter's assessment of the causal relationship of "death", "blood pressure increased", "chest pain", "diarrhoea", "dyspnoea exertional", "eye irritation", "injection site pain", "oropharyngeal pain", "oxygen saturation decreased", "pneumonia", "wound" and "heart rate increased" with the suspect product(s) BNT162b2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (18Apr2023): This is a non-interventional study follow up report received from a new contactable Other Health Professional from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number E2B_05977659. (Linked Regulatory Number E2B_03305971, E2B_03369525). This information was initially reported to Health Canada between 07Oct2022 and 12Dec2022 from an unknown Market Authorization Holder AER# CA2022034554.

Updated information included: added the seriousness criteria (death), new products: Influenza vaccine, azithromycin and cephalexin, new events: death, heart rate increased and Inappropriate schedule of product administration, new reporter (other HCP), removed the event 'hospitalization'.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on available information and known drug safety profile, a reasonable possibility that the events diarrhea and injection site pain are related to COVID-19 Vaccine- Manufacturer Unknown (BNT162B2) cannot be excluded. Conversely, all other events are assessed as unrelated to COVID-19 Vaccine. Lacking information on circumstances surrounding death and the cause of death, the case is managed as if there was a reasonable possibility that this patient's death is related to administration of the suspect product. This case will be reassessed should additional information becomes available.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Blood pressure increased	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chest pain	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diarrhoea	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea exertional	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Eye irritation	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Vaccination site pain	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Oropharyngeal pain	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Oxygen saturation decreased	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pneumonia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Wound	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Heart rate increased	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	**DOB of Parent** (B.1.10.2.1)	**Age** (B.1.10.2.2)	**LMP date** (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	**Medical history** (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06322378 (1)	Page#20

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
	Other studies

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)
Pharmaceutical Company	PFIZERINC
Department (A.3.1.3a)	**Title (A.3.1.3b)**

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
[redacted]		[redacted]

Street (A.3.1.4a)
17,300 Trans-Canada Highway

City (A.3.1.4b)	State (A.3.1.4c)
Kirkland	Quebec
Postcode (A.3.1.4d)	**Country code (A.3.1.4e)**
H9J 2M5	Canada
Tel No. (A.3.1.4f)	**Fax no. (A.3.1.4i)**

Email Address (A.3.1.4l)
CAN.AEReporting@pfizer.com

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)
Regulatory Authority	MHPD
Department (A.3.2.2b)	**Title (A.3.2.2c)**

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)
Postcode (A.3.2.3d)	**Country (A.3.2.3e)**
	Canada
Tel no. (A.3.2.3f)	**Fax no. (A.3.2.3i)**

Email address (A.3.2.3l)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06342725 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230419 CCYYMMDD
	HC Initial Received Date:	2023 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2023A052154()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230301 CCYYMMDD	20230418 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2023A052154

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
MC Canada AZPROD0000	[redacted] CA-AstraZeneca-2023A052154

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male	175 Centimeter	79.4 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1976[redacted] CCYYMMDD			45.442 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06342725 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)
26.0	Death

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3) ASKU	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Death	
Source of assessment (B.4.k.18.2) INITIAL REPORTER	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4) Yes

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Canada Vigilance AER#:	E2B_06342725 (1)	Page#3

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH #0

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report was received from a consumer. The report concerning a male patient of Caucasian ethnic origin (age 45 years, height 69 in, weight 175 lb).

No medical history concomitant products were reported.

On an unknown date, the patient received Astrazeneca Covid-19 Vaccine (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number ASKU), via intramuscular route, for an unknown indication.

On an unknown date, the patient experienced DEATH 0 (Preferred term- Death).

It was unknown if any action was taken with Astrazeneca Covid-19 Vaccine.

On [redacted] 2021, the patient died (MedDRA PT: Death).

An autopsy was performed. The cause of death was death 0 (confirmed at autopsy).

The reporter assessed the event DEATH 0 was considered to be serious due to seriousness criteria of death and important medical event.

The reporter assessed that there was a reasonable possibility of a causal relationship between Astrazeneca Covid-19 Vaccine and the following event: death 0.

All required follow-up attempts have been completed to obtain the Lot / Batch number for specify the biologic product, however the Lot / Batch number was not received.

Summary of follow-up information received by AstraZeneca on 18-Apr-2023 from consumer via spontaenous source: Summary of unsuccessful Lot/Batch number attempts added. Narrative updated.

AUTOPSY DETERMINED CAUSE OF DEATH: DEATH #0
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case concerns a 45-year-old male vaccinee with fatal event of Death in association with AZD1222. The cause of death was reported as DEATH #0, that was confirmed as such at autopsy. Due to limited information on baseline health condition of the patient before vaccination, relevant medical history, concomitant medication, date of vaccination, circumstances surrounding the event, risk factors, concomitant medication, medication history, detailed etiological and diagnostic workup, details of the autopsy report with confirmed final diagnosis, the evaluation did not find evidence to suggest a causal relationship between the fatal event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06342725 (1)	Page#5

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)
Pharmaceutical Company	AZPROD0000

Department (A.3.1.3a)	Title (A.3.1.3b)
Patient Safety	

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Patient Safety		Interface Organisation

Street (A.3.1.4a)
[redacted]

City (A.3.1.4b)	State (A.3.1.4c)
[redacted]	

Postcode (A.3.1.4d)	Country code (A.3.1.4e)
[redacted]	United Kingdom

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)
[redacted]	[redacted]

Email Address (A.3.1.4l)
Sapphire.BusinessSupport@astrazeneca.com

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)
Regulatory Authority	MHPD

Department (A.3.2.2b)	Title (A.3.2.2c)
Trading Partner Management Office	

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)
250 Lanark Avenue, Mail Stop 2005A

City (A.3.2.3b)	State (A.3.2.3c)
Ottawa	ON

Postcode (A.3.2.3d)	Country (A.3.2.3e)
K1A 0K9	Canada

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)
TPMO_BGPC@hc-sc.gc.ca

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Canada Vigilance AER#:	E2B_06365047 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230314 CCYYMMDD
	HC Initial Received Date:	20230314 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

US-MODERNATX, INC.-MOD-2023-714793(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230307 CCYYMMDD	20230307 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	US-MODERNATX, INC.-MOD-2023-714793

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
OCCC MODERNATX QMODERNAP	US-OCCC-CINT0003212 US-MODERNATX-MOC20230308000183 US-MODERNATX, INC.-MOD-2023-714793

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (1) E2B_06364488, (2) E2B_06365577

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			77 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_06365047 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5) 2.5 ML MULTIDOSE VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran davesomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02532352 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
Dose 3		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
{Specific product reported: No, product was inferred}		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MY WIFE HAD A THIRD JAB AND SHE PASSED AWAY A WEEK LATER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a consumer and describes the occurrence of DEATH (My wife had a third jab and she passed away a week later) in a 77-year-old female patient who received mRNA-1273 BIVALENT .222 (SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5)) for COVID-19 prophylaxis.

No Medical History information was reported.

On an unknown date, the patient received third dose of mRNA-1273 BIVALENT .222 (SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5)) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

For mRNA-1273 BIVALENT .222 (SPIKEVAX BIVALENT (ORIGINAL / OMICRON BA.4/5)) (Unknown), the reporter did not provide any causality assessments.

No concomitant medications were reported.
No treatment information was reported.

Company comment: This spontaneous case reported by a consumer, concerns a 77-year-old female patient with no reported medical history, who met with a fatal outcome (PT: Death). Death occurred about a week after administration of third dose of mRNA-1273.222 bivalent vaccine. Other details are not available for medical review. Exact cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273.222 bivalent vaccine is not affected by this report.

This case was linked to US-MODERNATX, INC.-MOD-2023-714580 (E2B Linked Report).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_06365047 (0)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) United States of America		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_06421845 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230410 CCYYMMDD
	HC Initial Received Date:	20230410 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2023AMR051169(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230406 CCYYMMDD	20230406 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-GLAXOSMITHKLINE-CA2023AMR051169

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZER 01052547635	CA-PFIZER-202201332624 CA-GLAXOSMITHKLINE-CA2023AMR051169

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) E2B_06438221

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - GLAXOSMITHKLINE

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			96 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06421845 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Canada Vigilance AER#:	E2B_06421845 (0)	Page#3

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** SHINGLES VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Prophylaxis
Start date of drug (B.4.k.12) 202[redacted] CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 31 Days	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** COVID-19	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** COVID-19	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Prophylaxis
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Canada Vigilance AER#:	E2B_06421845 (0)	Page#5

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ON [redacted] 2022 SHE DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	1 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
31 Days		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAD COVID

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	COVID-19
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	COVID-19

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
2 Days		Unknown

Summary (B.5)

Case narrative (B.5.1)

This serious case was reported by a consumer via other manufacturer and described the occurrence of unknown cause of death in a 96-year-old female patient who received Herpes zoster (Shingles vaccine) for prophylaxis.

Co-suspect products included COVID-19 VACCINE (COVID VACCINE) for prophylaxis.

On [redacted] 2021, the patient received Shingles vaccine. On an unknown date, the patient received COVID VACCINE. On [redacted] 2021, 2 days after receiving Shingles vaccine, the patient experienced covid-19 (Verbatim: had covid). On [redacted] 2022, the patient experienced unknown cause of death (Verbatim: On [redacted] 2022 she died) (serious criteria death and GSK medically significant). The outcome of the covid-19 was not reported. The patient died on [redacted] 2022. The reported cause of death was unknown cause of death.

It was unknown if the reporter considered the unknown cause of death and covid-19 to be related to Shingles vaccine.

It was unknown if the company considered the unknown cause of death and covid-19 to be related to Shingles vaccine.

Additional Information:
GSK Receipt Date: 06-APR-2023
The reporter had mentioned that when her mother had received a shingles vaccine and 2 days later her mother had covid and on [redacted] 2022, her mother died.
The reporter stated that, her mother had received all of her covid vaccines up till that point.
31 days after receiving Shingles vaccine, the patient experienced unknown cause of death.
It was unknown if the reporter had considered the adverse event to be related to the COVID -19 Vaccine.
The follow-up was not possible as per the process convention.
This case was linked with CA2023AMR051164, which was reported by same reporter.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_06447381 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230421 CCYYMMDD
	HC Initial Received Date:	20230421 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2023A091530()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20230418 CCYYMMDD	20230418 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2023A091530

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
MC Canada AZPROD0000	[redacted] CA-AstraZeneca-2023A091530

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_06447381 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Clot blood	
Source of assessment (B.4.k.18.2) INITIAL REPORTER	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4) Yes

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOTTING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Clot blood

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Thrombosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer. The report concerning a patient of unknown gender (age not provided) of Unknown ethnic origin.

No medical history was reported.

No concomitant products were reported.

On an unknown date, The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for covid-19 immunisation.

On an unknown date, the patient experienced blood clotting (preferred term: Thrombosis).

It was unknown if any action was taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml.

It was not known whether an autopsy was performed. On an unspecified date, The patient died from the event of blood clotting.

The cause of death was blood clotting.

The reporter assessed the event blood clotting to be serious due to seriousness criteria of death.

The reporter considered that there was a reasonable possibility of a causal relationship between Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml and the following event of blood clotting.CAUSE OF DEATH: BLOOD CLOTTING
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Thrombosis is not listed in company core data sheet of AZD1222. The cause of death was reported as Blood clotting. Due to limited information on vaccinee's age and gender, nature and circumstances leading to the events, date of vaccination, event onset date, relevant medical and family history, possible risk factors, detailed etiologic and diagnostic workup, the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

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Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_06447381 (0)	Page#5

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
PRIVACY

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
PRIVACY	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
PRIVACY	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)
Pharmaceutical Company	AZPROD0000

Department (A.3.1.3a)	Title (A.3.1.3b)
Patient Safety	

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Patient Safety		Interface Organisation

Street (A.3.1.4a)
[redacted]

City (A.3.1.4b)	State (A.3.1.4c)
[redacted]	

Postcode (A.3.1.4d)	Country code (A.3.1.4e)
[redacted]	United Kingdom

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)
[redacted]	[redacted]

Email Address (A.3.1.4l)
Sapphire.BusinessSupport@astrazeneca.com

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Receiver (A.3.2)

Type (A.3.2.1) Regulatory Authority		**Organization** (A.3.2.2a) MHPD
Department (A.3.2.2b) Trading Partner Management Office		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a) 250 Lanark Avenue, Mail Stop 2005A		
City (A.3.2.3b) Ottawa		**State** (A.3.2.3c) ON
Postcode (A.3.2.3d) K1A 0K9		**Country** (A.3.2.3e) Canada
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l) TPMO_BGPC@hc-sc.gc.ca		

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Canada Vigilance AER#:	E2B_06450510 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20230424 CCYYMMDD	
	HC Initial Received Date: 20230424 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2023A091529()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20230418 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20230418 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2023A091529

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) MC Canada AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** [redacted] CA-AstraZeneca-2023A091529

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Clot blood	
Source of assessment (B.4.k.18.2) INITIAL REPORTER	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4) Yes

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	TOZINAMERAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOTTING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer, concerning a patient of unknown age, gender and ethnic origin.

No medical history was reported. No concomitant products were reported.

On an unknown date, the patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for covid-19 immunisation.

On an unknown date, the patient started treatment with Covid-19 Vaccine Nos Manufacturer Unknown (bnt162b2) (tozinameran) Dose Unknown, unknown route for covid-19 immunisation.

On an unknown date, the patient experienced blood clotting (preferred term: Thrombosis).

It was unknown if any action was taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml and Covid-19 Vaccine Nos Manufacturer Unknown (bnt162b2).

On an unspecified date, the patient died from the event of blood clotting.

It was not known whether an autopsy was performed. The cause of death was blood clotting.

The reporter assessed the event of blood clotting to be serious due to seriousness criteria of death.

The reporter considered that there was a reasonable possibility of a causal relationship between Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml and the following event: blood clotting.CAUSE OF DEATH: BLOOD CLOTTING
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Thrombosis is not listed in the company core data sheet of AZD1222. The case of death was reported as BLOOD CLOTTING. Due to limited information on baseline health condition before vaccination, relevant family history, concurrent diseases, relevant medication history, date of vaccination, event onset date, details and circumstances surrounding the event, possible risk factors (obesity, injury or surgery, smoking, diabetes, high blood pressure, high cholesterol and immobility) and detailed diagnostic and etiologic workup (detailed autopsy report), the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_06450510 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
PRIVACY

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
PRIVACY	QU

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
PRIVACY	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)
Pharmaceutical Company	AZPROD0000

Department (A.3.1.3a)	Title (A.3.1.3b)
Patient Safety	

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Patient Safety		Interface Organisation

Street (A.3.1.4a)
[redacted]

City (A.3.1.4b)	State (A.3.1.4c)
[redacted]	

Postcode (A.3.1.4d)	Country code (A.3.1.4e)
[redacted]	United Kingdom

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)
[redacted]	[redacted]

Email Address (A.3.1.4l)
Sapphire.BusinessSupport@astrazeneca.com

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Receiver (A.3.2)

Type (A.3.2.1) Regulatory Authority		**Organization** (A.3.2.2a) MHPD
Department (A.3.2.2b) Trading Partner Management Office		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a) 250 Lanark Avenue, Mail Stop 2005A		
City (A.3.2.3b) Ottawa		**State** (A.3.2.3c) ON
Postcode (A.3.2.3d) K1A 0K9		**Country** (A.3.2.3e) Canada
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l) TPMO_BGPC@hc-sc.gc.ca		

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Canada Vigilance AER#:	000969752 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211001 CCYYMMDD
	HC Initial Received Date:	20211001 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR-20211001181451_96834()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
		Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Community -

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			90 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

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Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
booster shot		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Booster
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
1 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNRESPONSIVE TO ANY STIMULI

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unresponsive to stimuli		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Unresponsive to stimuli		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
1 Days			

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PALE AND WAXY IN APPEARANCE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pale		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pallor		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

EYES SUNKEN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Eyes sunken		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Lid sulcus deepened		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MAY HAVE HAD SYSTEMIC REACTION THAT HER BODY COULD NOT RECOVER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Systemic allergic reaction		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hypersensitivity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

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Summary (B.5)

Case narrative (B.5.1)

Resident had been increasingly lethargic the past month which resulted in low oral intake, specifically over the past three weeks. But when son came to visit on [redacted]2021 resident perked up and was alert, talkative, and drank an entire strawberry milkshake. Resident continued to be alert and talkative on [redacted]by HCAs.
The booster shot itself may not be responsible for the death, but I felt it was appropriate to file a report being that the drastic decline in health occurred within 24 hours of thr vaccine. She may have had a systemic reaction that her body could not recover from given her poor health prior to the third dose of the Pfizer vaccine but the family did not want an autopsy
---
Dhpr log details:
Safety Report ID: CA-DHPR-20211001181451_96834
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20211001
First Name: [redacted]
Last Name: [redacted]
Telephone: [redacted]
Ext.:
Address: [redacted]
City [redacted]
Province/Territory: [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization: [redacted]
Reporter Type: Nurse

Patient ID: [redacted]
Age: 90 Year(s)
Sex: Female
Height:
Weight:
Med History: Sciatica, osteoporosis, hypothyroidism, hypertension, dementia
Allergies: Codeine, sulfa

Serious Death: Yes
Date of Death: 2021[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Died
Reaction Start Date:
Reaction End Date:
Reaction Description: Resident received covid-19 Pfizer booster on [redacted]2021. The morning of [redacted] 2021 she was found to be unresponsive to any stimuli, pale and waxy in appearance, and, eyes sunken.
Palliative orders were received at 0915, resident was pronounced dead at 2150 on [redacted]2021.

Suspect Product 1
DIN #/NPN #:
Product Name: Pfizer Covid-19 booster shot
Strength:
Strength other:
Dosage form: Liquid
Manufacturer: Pfizer
Lot #:
Expiry date:
Product start date: 2021[redacted]
Product end date:
Dose:
Frequency:
Route of administration: Intramuscular
Route of administration - Other:
Indication: Booster shot
Reported to Mfr: No
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Not applicable
Dechallenge: N/A
Rechallenge: N/A

Concomitants: Resident had taken regularly scheduled medications up until the evening of [redacted]2021
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Sciatica	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Osteoporosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypothyroidism	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dementia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug allergy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Lethargic	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Oral intake reduced	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Sciatica, osteoporosis, hypothyroidism, hypertension, dementia
Allergies:Codeine, sulfa

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c) [redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)
Postcode (A.3.1.4d)	Country code (A.3.1.4e)
Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)
Postcode (A.3.2.3d)	Country (A.3.2.3e)
Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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2 | Serious adverse drug reaction reporting form for hospitals

* = required, if known (if information is in the control of or reasonably accessible by the hospital for mandatory reporting)
** = required (hospital is exempt from mandatory reporting if this information is unavailable)
Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the suspect product(s) caused or contributed to the serious adverse drug reaction(s).

A. General information

1. Type of report*	2. Health Canada reference no. (For follow-up reports only)
☒ Initial ☐ Follow-up	

3. Organization file no.	4. Date report submitted	5. Documentation date*
	2021-10-06	

6. a. Organization contact first name* / b. Last name*	7.a. Phone no.* (705) 649-3181 ext. [redacted] / b. Email [redacted] / c. Fax [redacted]
[redacted] / [redacted]	

8. Organization name* Waypoint centre for Mental Health Care

9. Source of report (profession)	10. Health Canada institutional ID (If ID provided, no need to provide address)
Pharmacist	

11. Address	12. City	13. Province / Territory	14. Postal code
[redacted]	[redacted]	[redacted]	[redacted]

15. Reason for seriousness* (explain (f) in section F)

☒ (a) Death (yyyy-mm-dd) 2021-[redacted] ☐ (b) Life-threatening ☐ (c) Disability ☐ (d) Congenital malformation
☐ (e) Caused/prolonged in-patient hospitalization ☐ (f) Required medical intervention to avoid any of (a) to (e)

B. Patient information

1. Patient ID (e.g. initials, record no.)	2. Sex**	3. Age**	4. Height	5. Weight
[redacted]	Male	77 Year(s)	154 cm or ft in	89 kg or lbs oz

6. Known medical conditions and relevant lifestyle factors* (e.g. hepatic and/or renal impairment, diabetes mellitus, current pregnancy, tobacco, cannabis or alcohol use, recreational drug use, etc.).

Patient had Liver cancer with Bilateral pulmonary mets, Ascitis, Congestive Heart failure, Emphysema-COPD, Kidney dysfunction,Anemia, Hypothyroidism. Patient was palliative status

7. Known allergies* (e.g. food, drugs, environmental, etc.; provide details).

NKA

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3 | Serious adverse drug reaction reporting form for hospitals

C. Serious adverse drug reaction(s)

1. Did the patient recover?* (please choose one of the following)	2. Reaction start date*	3. Reaction end date*
☐ Recovered ☐ Recovering ☐ Not recovered ☒ Died ☐ Unknown ☐ Recovered with sequelae		

4. Description of the serious adverse drug reaction(s)**

No serious adverse reaction was observed. Patient received 3rd dose of COVID vaccine on [redacted] and had 2 previous vaccines with no adverse effects. Patient was found on the floor beside his bed at 10:10am on [redacted]/21 and was unresponsive. Patient had metastatic liver cancer, was refusing treatment and was palliative. Due to palliative state, no autopsy was performed.

D. Suspect product one

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known
This information is important for traceability of an adverse reaction to a specific suspect product

1. Drug identification number (DIN)*	2. Identifying code for urgent public health need drugs**
02509210	
3. Brand name (per product label)**	**4. Common/proper name** (active ingredient)**
Pfizer Covid-19 Vaccine -Comirnaty	TOZINAMERAN
5. Strength (per unit)	**6. Dose**
30 MCG / 0.3 ML	30 µg microgram(s)

7. Frequency
Dose administered on [redacted] @ 10:35 am

8. Dosage form (e.g. tablet, powder, liquid) injection

9. Route of administration	10. Product start date*	11. Product end date*
Intramuscular	2021-[redacted]	2021-[redacted]

12. Indication
Covid-19 Immunization dose#3

13. Lot no.	14. Expiry date
FD7206	2021/11/30

15. a. Manufacturer name
Pfizer

b. Did you also report to the manufacturer?*
☐ Yes ☒ No

c. Date reported

d. Reference no.* (if known)

16. What action was taken?
Not applicable

17. Did the reaction stop if dose was reduced or removed?
☐ Yes ☐ No ☐ Unknown ☒ N/A

18. Did the reaction return with reintroduction of the product?
☐ Yes ☐ No ☐ Unknown ☒ N/A

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4 | Serious adverse drug reaction reporting form for hospitals

D. Suspect product two

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug identification number (DIN)*	2. Identifying code for urgent public health need drugs**
3. Brand name** (per product label)	4. Common/proper name** (active ingredient)
5. Strength (per unit)	6. Dose

7. Frequency

8. Dosage form (e.g. tablet, powder, liquid)

9. Route of administration	10. Product start date*	11. Product end date*

12. Indication

13. Lot no. 28195DK	14. Expiry date 2023-04-01
15. a. Manufacturer name b. Did you also report to the manufacturer?* ☐ Yes ☒ No c. Date reported d. Reference no.* (If known)	16. What action was taken? 17. Did the reaction stop if dose was reduced or removed? ☐ Yes ☐ No ☐ Unknown ☒ N/A 18. Did the reaction return with reintroduction of the product? ☐ Yes ☐ No ☐ Unknown ☒ N/A

E. Concomitant therapeutic product(s)

1. Known therapeutic product(s) taken or used at the same time the reaction occurred* (e.g. prescription and non-prescription drugs, medical devices, natural health products, etc. Include details of use if available).

No medication changes happened in the week leading up to the COVID vaccine booster dose. Medications the patient was taking were:
Fluticasone/Salmeterol (Advair 250Mcg/25Mcg Inhaler) — 2 Puffs BID
Diclofenac cream (Voltaren Emulgel 1.16%)- — topically TID
Propylene Glycol/Peg (Secaris Nasal Gel) — topically BID
Tiotropium (Spiriva 18 Mcg) 1 CAP – ———Inhale contents of 1 capsule daily.
Furosemide (Lasix or Equivalent) 20 MG TAB——3 tablets (60mg) po daily
lamoTRIgine (LaMICtal OR EQUIVALENT) 100 MG TAB— 1 tablet (100mg) po daily
lamoTRIgine (LaMICtal OR EQUIVALENT) 25 MG TAB---- 1 tablet (25mg) po daily
Levothyroxine (Synthroid) 25 MCG TAB ----- 1 tablet (25MCG) po daily
Polyethylene Glycol 3350 (Restoralax, Lax-A-Day)---- 1 PACK po daily
Pantoprazole EC (Pantoloc or Equivalent) 20 MG— 1 tablet (20mg) po QAM
Potassium Chloride Sr (Slow-K, Apo-K) 8 MEQ TAB---- 1 tablet (8 MEQ) po QAM
HYDROmorphone (Dilaudid or Equivalent) 0.5 MG HALFTAB — One Half tablet (0.5mg) po at 800 and 1400

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5 | Serious adverse drug reaction reporting form for hospitals

F. Additional information

1. Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to the assessment of the serious adverse drug reaction(s).

-There were no medication changes in the week proceeding to his deceased date. Patient received his COVID vaccine booster dose on [redacted] 2021 at 10:35 am. No PRNs were administered on [redacted] 2021. No adverse reaction from the vaccine was noted for the booster dose, or the two previous administrations of the COVID vaccine.

As per records patient has Metastatic liver cancer that did apread and patient was deemed palliative, As per records patient refused oncology treatment and the treatment goal relied on comfort meeasures and palliative approach.

As per Dr [redacted] report the patient passed away from natural causes. The patient safety incident entered indicates that the patient was found on the floor next to the bed around 10:10am and was deceased. A fall out of bed is suspected.

No autopsy was performed due to the palliative status of the patient

-A causal relationship between the vaccine and the patient death is not suspected however the wording on the Health Canada website encourages reporting of incidents in the absence of a causality assessment or investigation to determine whether the therapeutic product caused the serious ADR

-Report of Adverse Event Following Immunization (AEFI) was completed and sent to the local public health unit.

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Instructions on completing the serious adverse drug reaction (ADR) reporting form for hospitals

A. General information

A1. **Initial or follow-up*:** Indicate whether the report is the first one submitted for this specific adverse drug reaction (i.e. initial) or a follow-up to a previously submitted report.

A2. **Health Canada reference number:** If the report is identified as a follow-up in A1, provide the reference number of the serious ADR report generated by Health Canada and provided to the submitter further to initial report submission.

A3. **Organization file number:** Indicate the hospital's identification number for the case. For follow-up reports, the file number should be the same as the number assigned to the initial report.

A4. **Date submitted:** Indicate the date the report was sent to Health Canada.

A5. **Documentation date*:** Indicate the date when the hospital first documented this serious ADR.

A6. **Organization contact first & last name*:** Enter the first and last name of a contact for the hospital.

A7. **Phone number, email or fax*:** Enter the telephone number, email address or facsimile number to contact in the case of follow-up.

A8. **Organization name*:** Enter the full name of the reporting hospital.

A9. **Source of report:** Indicate the profession of the hospital employee who first flagged this as a potential serious ADR.

A10. **Health Canada institutional ID:** Indicate the submitter's unique hospital identifier as assigned by Health Canada. To obtain this identifier, please contact hc.canada.vigilance.sc@canada.ca. Address details do not need to be completed if this unique number is provided.

A11. **Hospital address:** Enter the civic address for the hospital.

A12. **City:** Indicate the city in which the hospital is located.

A13. **Province/Territory:** Select the province or territory in which the hospital is located.

A14. **Postal code:** Provide the postal code of the hospital.

A15. **Reason for seriousness*:** Select a criterion that makes the report a serious adverse reaction. More than one can be selected. Enter the date of death if known.

B. Patient information

B1. **Patient ID:** Provide a patient identifier in order to readily locate the case for follow-up purposes. This can be the patient's initials or the record number. Please do not provide the full name of the patient.

B2. **Sex**:** Enter the patient's biological sex. Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male.

B3. **Age**:** Provide the patient's age at the time of the reaction.

B4. **Height:** Enter the patient's height.

B5. **Weight:** Enter the patient's weight.

B6. **Known medical conditions and lifestyle factors*:** If available, provide information on the patient's history and other known conditions.

B7. **Known allergies*:** Provide the allergies the patient is known to have experienced, whether to food, drugs, environmental components, etc.

C. Serious adverse drug reaction(s)

C1. **Recovery status*:** Indicate the outcome of the serious ADR.

C2. **Reaction start date*:** Provide the date of onset of the serious ADR. Partial dates are acceptable

C3. **Reaction end date*:** Provide the end date of the serious ADR if applicable. Do not provide this for reports involving death. Partial dates are acceptable.

C4. **Description of the serious adverse drug reaction(s)**:** List the serious adverse drug reaction(s) that the patient experienced. Please try to avoid use of acronyms in this section.

D. Suspect product(s)

Up to two suspected products may be reported on one form. Attach additional forms if there are more than two suspected products for the reported serious ADR.

Reporting of product-specific identifiers is important for traceability of an adverse reaction to a specific suspect product. The drug identification number (DIN) is a unique identifier for all drug products sold in Canada. If the DIN is unknown, biologic drugs including biosimilars can be uniquely identified by providing their brand name. Generic drugs can be uniquely identified by providing both the generic name and the manufacturer name. Please also include the lot number, if known.

D1. **Drug identification number (DIN)*:** Provide the drug identification number of the product the patient took, if available. For drugs accessed under an urgent public health need, provide the identifying code or number for the country in which the product is marketed. If the DIN is provided, it is not necessary to provide manufacturer, product name, active ingredient(s), strength, or dosage form.

D2. **Identifying code for urgent public health need drugs**:** If the drug was imported as part of the access to drugs in exceptional circumstances, provide the code or number of the drug, if any, assigned in the country in which the drug was authorized for sale.

D3. & D4. Brand name, common/proper name:** Provide the brand name as per the product label if the DIN is not known. If the brand name cannot be provided, or is not specific (e.g. an active ingredient as brand name), please provide the proper name (active ingredients) and the manufacturer name.

D5. **Strength:** Provide the amount of active ingredient per single dosage form of the drug. For example, if the patient took two tablets of a medication, please provide the strength of only one tablet. Strength is defined as the amount of an active ingredient that the product contains.

D6. **Dose:** Indicate the amount of the product taken by the patient per the dosing regimen. Dose is normally expressed as a quantity.

D7. **Frequency:** Indicate how often the dose was taken by the patient. Shorthand text, such as b.i.d., is acceptable in this field.

D8. **Dosage form:** Indicate the dosage form of the product (e.g. tablet, powder, liquid)

D9. **Route of administration:** Provide the means by which the drug entered the patient's body. The top five most common routes of administration are at the top of the dropdown list.

D10. **Product start date*:** Indicate the date on which the patient started using the product. If the exact date is not known, partial dates are acceptable.

D11. **Product end date*:** Indicate the date the patient stopped using the product, if applicable. Please only enter data in this field if it is known that the patient stopped taking the product. Partial dates are acceptable.

D12. **Indication:** Enter the therapeutic reason for use.

D13. **Lot no.:** If known, indicate the lot number(s) of the suspect product.

D14. **Expiry date:** If known, indicate the expiry date.

D15. **Manufacturer details*:** Indicate the manufacturer name of the suspect product and if the adverse reaction details were also provided to the manufacturer. If so, please also provide the date on which the case was reported to the manufacturer and the reference number if known.

D16. **Action taken:** Indicate what action was taken with the product.

D17. **Reaction stopped if dose was reduced or removed:** Indicate if the adverse reaction stopped after the suspect product was discontinued or the dose was reduced.

D18. **Reaction returned with reintroduction:** Indicate if the adverse reaction reappeared after the suspect product was reintroduced.

E. Concomitant therapeutic product(s)

E1. **Concomitant therapeutic products*:** List all known health products, other than the suspect product, the patient was taking at the same time (i.e. concomitantly) the reaction occurred. Information related to therapy details of these products is not required but encouraged. Do not include health products used to treat the reaction.

F. Additional information

F1. This section can be used to provide a narrative summary of the serious adverse drug reaction, additional information on the underlying diagnosis that is pertinent to the reaction, or information that did not fit in the structured fields that could help to determine why the reaction occurred. For serious cases involving death, this section can also be utilized to provide details on the official cause of death and autopsy results.

For more details, refer to the Guidance Document for hospitals at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospitalreporting/drugs-devices.html

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Fax Call Report HP LaserJet **M3035 MFP Series**

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Fax Header Information

[redacted]

2021-Oct-08 07:53

Job	Date/Time	Type	Identification	Duration	Pgs	Result
1765	2021-Oct-08 07:51	Send	[redacted]	1:11	0	No answer (0)

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[redacted]

FAX REPORT

ATIA - 19(1)

Dept./Program: Quality, Patient Safety & Risk

Date: October 8, 2021	Number of Pages: 7 (includes cover page)
To: Canada Vigilance Program	From: [redacted]
Re: ADR [redacted]	Title: Patient Safety, Quality Improvement Coordinator
Fax: 1-866-678-6789	Fax [redacted]
Tel: 1-866-234-2345	Tel: [redacted] ext. [redacted]
E-mail: hc.canada.vigilance.sc@canada.ca	E-mail: [redacted]

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Health Canada / Santé Canada

Protected "B" when completed

Serious adverse drug reaction reporting form for hospitals

Canada Vigilance - Adverse reaction reporting program

For best results, download and open this form in a PDF reader.

Privacy notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information Health Canada needs to administer the Canada Vigilance adverse reaction reporting program authorized under the *Department of Health Act*, section 4 and the *Food and Drug Regulations*, Section C.01.020.

Purpose of collection: Health Canada requires this information to assess adverse reaction reports, monitor the safety of health products and enforce relevant legislation where applicable. Personal information may be used to analyze general trends, report to senior management and evaluate related programs and services. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools and/or responses to inquiries. A subset of de-identified Canada Vigilance adverse reaction reporting program data is made publicly available from the Canada Vigilance adverse reaction online database.

Other uses or disclosures: Personal information may be shared within Health Canada and with the Public Health Agency of Canada, the Canadian Medication Incident Reporting and Prevention System Program (managed in partnership with the Canadian Institute for Health Information, the Institute for Safe Medication Practices Canada, and the Canadian Patient Safety Institute), and international regulatory and health product monitoring authorities, for monitoring adverse reactions. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: This personal information collection is described in Info Source, available online at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a26. Refer to the personal information bank HC PPU 417.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to, and correction of, your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's privacy coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Submission methods

Electronic reporting
If you are interested in submitting reports electronically (e.g. secure file transfer protocol - sFTP) to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca

Fax
Download, complete and print the Serious adverse drug reaction reporting form for hospitals.
Send by fax at: 1-866-678-6789

Mail it to the Canada Vigilance National Office
Canada Vigilance Program
Health Products Surveillance and Epidemiology Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Address Locator 1908C
Ottawa, Ontario
K1A 0K9

If you have any questions related to mandatory reporting for hospitals, you may contact the Canada Vigilance Program by:
Email: hc.canada.vigilance.sc@canada.ca
Toll-free telephone: 1-866-234-2345

Canada

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ATIA - 19(1)

FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1 866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI*

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
65 ans _____ mois	☐ Homme ☒ Femme	_____ cm 5 pi 9 po	_____ kg 95 lbs _____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

Démence sévère
Cholécystectomie 2009
Prothèse totale de la hanche 2018

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]	[redacted]	[redacted]

4. Adresse	5. Courriel
[redacted]	[redacted]

6. Langue préférée	7. Organisation (le cas échéant)
☒ français ☐ anglais	[redacted]

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ☐ Médecin ☐ Pharmacien

☒ Autre professionnel de la santé (spécifier) : Infirmière

9. Cela a-t-il été déclaré au fabricant?

☐ Oui ☒ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

- ☒ Décès (fournir la date) 2021[redacted]
- ☐ Met la vie en danger
- ☐ Hospitalisation
- ☐ Prolongation d'une hospitalisation
- ☐ Incapacité
- ☐ Malformation congénitale
- ☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

☐ Oui ☒ Non ☐ Inconnu

☐ En cours de rétablissement (expliquer) : _____

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)
2021[redacted]	202[redacted]

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

Voir document en annexe

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
Vaccin Covid-19		Moderna

4. N° du lot	5. N° du DIN / N° du NPN
052C21A (vaccin covid)	

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
☐ Canada ☐ États-Unis ☐ Autre (spécifier) : _____	☐ Pharmacie ☐ Épicerie ☐ Internet ☐ Autre (spécifier) : [redacted]

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021[redacted]	202[redacted]

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
0.5mL	1 dose	Intramusculaire

13. Pourquoi le produit a-t-il été pris/prescrit?*

Recommandation de la santé publique

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☐ Oui ☐ Non	☐ Oui ☐ Non ☒ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ☐ Non ☒ Ne s'applique pas	☐ Oui ☐ Non ☒ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

- ☐ Certain
- ☐ Probablement/vraisemblablement
- ☒ Possiblement
- ☐ Pas disponible / incapable de vérifier
- ☐ Improbable
- ☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

Vaccin Fluzone HD Quadrivalent (voir 2e formulaire)

20. Tests/données de laboratoire pertinents

* Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

Pub. : 150143 | Date : avril 2020

Santé Canada Health Canada

Canada

A2023000085

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ATIA - 19(1)

FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI*

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
65 ans _____ mois	☐ Homme ☒ Femme	_____ cm 5 pi 9 po	_____ kg 96 lbs _____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

Démence sévère
Cholécystectomie 2009
Prothèse totale de la hanche 2018

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]	[redacted]	[redacted]

4. Adresse	5. Courriel
[redacted]	[redacted]

6. Langue préférée	7. Organisation (le cas échéant)
☒ français ☐ anglais	[redacted]

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ☐ Médecin ☐ Pharmacien

☒ Autre professionnel de la santé (spécifier) : Infirmière

9. Cela a-t-il été déclaré au fabricant?

☐ Oui ☒ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

☒ Décès (fournir la date) 2021-[redacted]
☐ Met la vie en danger
☐ Hospitalisation
☐ Prolongation d'une hospitalisation
☐ Incapacité
☐ Malformation congénitale
☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

☐ Oui ☒ Non ☐ Inconnu

☐ En cours de rétablissement (expliquer) : _____

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)
2021[redacted]	2021[redacted]

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

Voir document en annexe

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
Vaccin Influenza Fluzone HD Quadrivalent		Sanofi Pasteur

4. N° du lot	5. N° du DIN / N° du NPN
UJ727AB	02500523

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
☐ Canada ☐ États-Unis ☐ Autre (spécifier) : _____	☐ Pharmacie ☐ Épicerie ☐ Internet ☐ Autre (spécifier) [redacted]

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021[redacted]	2021[redacted]

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
0.5mL	1 dose	Intramusculaire

13. Pourquoi le produit a-t-il été pris/prescrit?*

Recommendation de la santé publique

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☐ Oui ☐ Non	☐ Oui ☐ Non ☒ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ☐ Non ☒ Ne s'applique pas	☐ Oui ☐ Non ☒ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

☐ Certain
☐ Probablement/vraisemblablement
☒ Possiblement
☐ Pas disponible / Incapable de vérifier
☐ Improbable
☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

Vaccin Covid-19 MODERNA (voir formulaire)

20. Tests/données de laboratoire pertinents

*Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

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ATIA - 19(1)

Raison du décès déclaré par le médecin traitant : Embolie Pulmonaire + probable, pas d'évidence de surinfection. Il est à noter que la religieuse est de niveau de soins 4, soins de confort, d'où l'origine des évaluations sommaires mentionnées ci-bas

Comme le décès est survenu moins de 7 jours suivant la 3e dose du vaccin contre la Covid et contre l'influenza, il est possible de croire qu'un lien existe. La religieuse ne présente aucun problème associé à la coagulation et n'a aucun antécédent cardiaque.

[redacted]

8h00 : Léthargie, tachypnée 32, sat 98% A.A., 138/81, pls 90, temp 36.1

14h00: Respiration rapide, faciès rouge, TA 93/46, sat 95% Air ambiant, pls 84. Jugulaire très distendue

14h30: respiration 38/min, sat 90%-95%. À l'auscultation, pas de bruits anormaux mais murmures vésiculaires audibles dans trois plages pulmonaires. Jugulaire, carotide et veines bras gch gonflées ++. fréquence cardiaque normale, auscultation cardiaque normale. Œdème aux MI. Médecin prescrit versed sous-cutané.

16h00 : Respiration 27/min mais en Cheyne-Stoke, sat 95% sur 2L/min via canule nasale. État de conscience stuporeux, présence de gémissement et d'agitation. Versed augmenté, dilaudid administré.

Ensuite entre 16h00 le [redacted] et 13h35 le [redacted] jugulaire et veine du bras gauche toujours très gonflées. Respiration cheyne-stoke., épisode d'apnée de 33 secondes, saturation variable entre 91-98% sur 2L/min. Présence de sécrétion dans la trachée, scopolamine débutée. Ensuite semble confortable avec Versed, dilaudid et scopolamine.

[redacted] 13h35 :

Décès

Suite au décès, apparition d'un grand hématome côté gauche du cou, de l'oreille à la base du cou et de 1 pouce derrière l'oreille à 1 pouce devant l'oreille.

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ATIA - 19(1)

DE: [redacted]

À: SANTÉ CANADA, DÉCLARATION DES EFFETS SECONDAIRES

DATE D'ENVOI: 4 NOVEMBRE 2021

Nb. PAGE: 3 excluant celle-ci

HC-SC REC'D 19-OC-2021 09:21:43 10-19-2021 1/1

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FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

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Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI**

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A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
72 ans ____ mois	■ Homme ☐ Femme	166 cm ____ pi ____ po	141 kg ____ lbs ____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

obésité morbide
troubles neurocognitifs majeurs
hydrocéphalie normotensive
HTA, DLPD, IRC, dépression

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]	[redacted]	[redacted]

4. Adresse	5. Courriel
[redacted]	[redacted]

Langue préférée	7. Organisation (le cas échéant)
■ français ☐ anglais	hopital

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ■ Médecin ☐ Pharmacien

☐ Autre professionnel de la santé (spécifier) : _____

9. Cela a-t-il été déclaré au fabricant?

☐ Oui ■ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

■ Décès (fournir la date) 2021 [redacted]
☐ Met la vie en danger
☐ Hospitalisation
☐ Prolongation d'une hospitalisation
☐ Incapacité
☐ Malformation congénitale
☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

☐ Oui ■ Non ☐ Inconnu

☐ En cours de rétablissement (expliquer) : _____

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

questionnement sur imputabilité
survenue 3 jours aprés la 1ere dose du vaccin moderna

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
vaccin COVID		Moderna

4. N° du lot	5. N° du DIN / N° du NPN

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
■ Canada ☐ Etats-Unis ☐ Autre (spécifier) : _____	■ Pharmacie ☐ Épicerie ☐ Internet ☐ Autre (spécifier) : _____

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021 [redacted]	

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)

13. Pourquoi le produit a-t-il été pris/prescrit?*

proposé pendant l'hospitalisation du patient en prévention tel qur recommandé

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
■ Oui ☐ Non	■ Oui ☐ Non ☐ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ■ Non ☐ Ne s'applique pas	☐ Oui ☐ Non ☐ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

☐ Certain	☐ Pas disponible / incapable de vérifier
☐ Probablement/vraisemblablement	■ Improbable
☐ Possiblement	☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

aucun

20. Tests/données de laboratoire pertinents

en cours d'invertigation cardio respiratoire

** Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

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Santé Canada Health Canada

Canada

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ATIA - 19(1)

FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

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Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI*

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
72 ans _____ mois	■ Homme □ Femme	166 cm _____ pi _____ po	141 kg _____ lbs _____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

obésité morbide
troubles neurocognitifs majeurs
hydrocéphalie normotensive
HTA, DLPD, IRC, dépression

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]	[redacted]	[redacted]

4. Adresse	5. Courriel
[redacted]	[redacted]

Langue préférée

■ français
□ anglais

7. Organisation (le cas échéant)

hopital

8. Choisir ce qui vous décrit le mieux

□ Consommateur ou autre non-professionnel de la santé ■ Médecin □ Pharmacien

□ Autre professionnel de la santé (spécifier) : _____

9. Cela a-t-il été déclaré au fabricant?

□ Oui ■ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

■ Décès (fournir la date) 2021[redacted]
□ Met la vie en danger
□ Hospitalisation
□ Prolongation d'une hospitalisation
□ Incapacité
□ Malformation congénitale
□ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

□ Oui ■ Non □ Inconnu

□ En cours de rétablissement (expliquer) : _____

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

questionnement sur imputabilité
subite 3 jours aprés la 1ere dose du vaccin moderna

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
vaccin COVID		Moderna

4. N° du lot	5. N° du DIN / N° du NPN

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
■ Canada □ États-Unis □ Autre (spécifier) : _____	■ Pharmacie □ Épicerie □ Internet □ Autre (spécifier) : _____

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021[redacted]	

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)

13. Pourquoi le produit a-t-il été pris/prescrit?*

proposé pendant l'hospitalisation du patient en prévention tel qur recommandé

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
■ Oui □ Non	■ Oui □ Non □ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
□ Oui ■ Non □ Ne s'applique pas	□ Oui □ Non □ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

□ Certain
□ Probablement/vraisemblablement
□ Possiblement
□ Pas disponible / incapable de vérifier
■ Improbable
□ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

aucun

20. Tests/données de laboratoire pertinents

en cours d'invertigation cardio respiratoire

Health Canada Santé Canada
[redacted]
M.N.P.D. / D.P.S.C.

* Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

Pub. : 150143 | Date : avril 2020

Santé Canada Health Canada

Canada

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ATIA - 19(1)

Tropiano, Stephano (HC/SC)

From: Canada Vigilance (HC/SC) <canadavigilance@hc-sc.gc.ca>
Sent: 2021-11-08 3:00 PM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Cc: Harland, Claire (HC/SC)
Subject: FW: PUB-001651- Covid Vaccine

Categories: Covid

Hello EFAX,

Please see below death report for DE.

Could you please provide the AER number to Claire (cc)

@Claire, can I assign this one to you?

Y:\HC\HPFB\MHPD\MHPSEIB-PROS\COMMUNICATIONS GC2\ENQUIRIES\Correspondence\Public\2021\PUB-001651-[redacted]

Thanks ☺
Lynda

From: Info (HC/SC) <info@hc-sc.gc.ca>
Sent: 2021-11-08 2:15 PM
To: [redacted]
Subject: RE: Covid Vaccine

Thank you for contacting Health Canada.

Your recent enquiry has been redirected to the appropriate area for a response.

Sincerely,

Health Canada | Santé Canada
Ottawa, Canada K1A 0K9
info@hc-sc.gc.ca
Telephone | Téléphone 613-957-2991 / Toll free | Sans frais 1 866-225-0709 /
Facsimile | Télécopieur 613-941-5366 / Teletypewriter | Téléimprimeur 1 800-267-1245
Government of Canada | Gouvernement du Canada

From: [redacted]
Sent: 2021-09-16 11:50 AM
To: Info (HC/SC) <info@hc-sc.gc.ca>
Subject: Covid Vaccine

To whom it may concern:

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My mother just passed away on [redacted] 2021. Her diagnosis was Leukemia, my mother has had several blood tests done over the past couple of years due to chronic pain and this low white blood cell count never showed up in a lab report. The hospital informed us that my mother had also had a stroke which took place 2 weeks earlier coincidentally the same time as her second covid vaccine. After receiving the second shot we did notice an almost lethargic like side effect along with increased confusion, lack of appetite and poor mobility. Myself and my family believe that what has happened to my mother is a result of the covid vaccine and would like to know how to go further to investigate her death. The hospital did state that the leukemia was recent and aggressive, it was Acute Myeloid Leukemia.

If you could advise us where to go from here we would appreciate it.

Regards,

[redacted] RPN
[redacted]

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FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI*

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
94 ans ___ mois	☒ Homme ☐ Femme	___ cm ___ pi ___ po	___ kg ___ lbs ___ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]		

4. Adresse	5. Courriel
[redacted]	

6. Langue préférée	7. Organisation (le cas échéant)
☐ français ☒ anglais	[redacted]

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ☐ Médecin ☐ Pharmacien

☒ Autre professionnel de la santé (spécifier) : INFIRMIÈRE

9. Cela a-t-il été déclaré au fabricant?

☐ Oui ☒ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

☐ Décès (fournir la date) ___
☐ Met la vie en danger
☐ Hospitalisation
☐ Prolongation d'une hospitalisation
☒ Incapacité
☐ Malformation congénitale
☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

☐ Oui ☒ Non ☐ Inconnu

☐ En cours de rétablissement (expliquer) : ___

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)
2021-[redacted]	2021-[redacted]

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

- léthargique
- INCONSCIENT
- Subacute hemorrhagie
- DÉCÈS

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
MODERNA, COVID-19 VACCIN	0.20 mg/ml	MODERNA

4. N° du lot	5. N° du DIN / N° du NPN
052C 21A	02510014

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
☒ Canada ☐ États-Unis ☐ Autre (spécifier) : ___	☒ Pharmacie ☐ Épicerie ☐ Internet ☐ Autre (spécifier) : ___

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021-10-29	2021-10-29

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
0.5 ml		Intra Muscular

13. Pourquoi le produit a-t-il été pris/prescrit?*

TROISIEME DOSE VACCINATION COVID

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☐ Oui ☐ Non	☐ Oui ☐ Non ☐ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ☒ Non ☐ Ne s'applique pas	☐ Oui ☐ Non ☐ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

☐ Certain
☐ Probablement/vraisemblablement
☐ Possiblement
☒ Pas disponible / incapable de vérifier
☐ Improbable
☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

20. Tests/données de laboratoire pertinents

* Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

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Nov. 23. 2021 7:58AM

Santé Canada / Health Canada

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-03-11 2:21 PM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: RE: Health Canada Follow-Up Clarification Request

EXTERNAL

Re: Health Canada Follow-Up Clarification Request

Good afternoon Mr. [redacted]

Please allow us first to convey our deepest regrets with the recent loss of your father. We offer you our most sincere condolences during this difficult time of grief.

We are contacting you today to confirm receipt of the adverse event following immunization (AEFI) report submitted to the Canada Vigilance Program on March 2nd, 2021 regarding your father and the use of the Moderna COVID-19 Vaccine.

As the result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified the present individual case safety reports (ICSRs) where clarification is needed in order to complete the case evaluation.

We acknowledge that this is a challenging time to be requesting additional information from you. If it is easier, you may wish to request your father's physician or other health care provider to assist you, or to submit a reply on your behalf. Any information would be greatly appreciated.

Canada Vigilance Case Number	Clarification Requested
000941232	Would you kindly have any information of the following: ○ Please provide any information regarding medical confirmation of the details provided in the report. ○ Please provide any information regarding the official cause of death. If an autopsy was performed, please provide any available details. ○ Please provide any additional details of the patient's condition after the second dose of the vaccine. Specifically, any information pertaining to the patient's vital signs including oxygen saturation. ○ Please provide any information pertaining to any laboratory test results. ○ Please provide any information regarding results of COVID testing both prior to and after the second dose.

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	○ Please provide any details regarding the treatment after the second vaccination. ○ Please provide the vaccine lot number.

May you please kindly respond to both myself, Michelle Séguin: michelle.seguin@canada.ca in addition to the Canada Vigilance COVID-19 Vaccine generic account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca).

Or, if you prefer, you may fax the requested information to the **Canada Vigilance Program fax at 1-866-678-6789**; please cite **case number 000941232** if replying by this means.

If you require further information within the scope of this request, please do not hesitate to contact me.

We thank you once again for your time.

Sincerely,

Michelle Séguin on behalf of:
The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: [redacted]
Sent: 2021-03-23 8:10 PM
To: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC); Seguin, Michelle (HC/SC)
Subject: Re: Health Canada Follow-Up Clarification Request

Michelle,
My father's doctor at the time is Dr. [redacted] medical clinic in [redacted] He was in the long term care facility in [redacted] bc of dementia. I did not receive the report and I contacted him by phone to express my concerns about the timing of the vaccine being administered and his subsequent onset of symptoms and deterioration. Dr. [redacted] had said it was not his opinion that this was a reaction at the time of the call although he did say that it was to my sister at the care facility??? This is not meant to be an attack on Dr. [redacted] or the staff who were caring for my father. This is an attempt to ensure that this is documented as to avoid potential future reactions.

- After my fathers death I called Dr [redacted] and he informed me that the death certificate attributed his death to complications to a suspected aspiration pneumonia, at this time I asked if he had considered the reaction to the vaccination, he had not.
- no autopsy was performed
These are the events as I remember them,
- as I said in my initial email that the next day after receiving the 2nd dose his O2 saturation dropped into the 80's his heart rate elevated, respiratory rate elevated, and he developed a fever
-at the time of the 2nd dose my father had been at the facility for 5 weeks and was not thriving. He was not eating well, taking fluids and had lost almost 20lbs. (my concern is that this condition had put him in a immune compromised condition which contributed to the adverse rx, Dr. [redacted] did not agree)
- I expressed at the time that he was experiencing a reaction to the second dose of his vaccine the nurse disagreed
- He was then put on O2, given fluids by IV and an antibiotic (the antibiotic may have been the next day)
- the dx of an aspiration was due to his crackly cough, I disagreed with this assessment because the cough was not new and had been present for more than a week as a result of the thrush he developed secondary to being on an antibiotic for i believe a UTI, He was sent for a chest x-ray the next day and this came back as not being inconclusive for the dx of pneumonia
- considering by fathers personal directive the discussion was had on if treatment should be pursued or let life take its course. Dr. [redacted] felt it was worth trying and care continued for the week.
-as long as he was on O2 and getting IV fluid his O2 saturation was in the 90's and his fever was under control
-After a week of this care it was determined that he was not responding and per his personal directive all measures were discontinued
-I do not know the results of his testing after the onset of his symptoms, I do not believe he was diagnosed with Covid as we were still allowed access to him
- I was not given the vaccine lot number

This is my recollection of the events surrounding my fathers reaction to the second dose of maderna vaccine, I hope this helps,

Sincerely
[redacted]

On Thu, Mar 11, 2021 at 12:21 PM Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca> wrote:

EXTERNAL

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	○ Please provide any information pertaining to any laboratory test results. ○ Please provide any information regarding results of COVID testing both prior to and after the second dose. ○ Please provide any details regarding the treatment after the second vaccination. ○ Please provide the vaccine lot number.

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We thank you once again for your time.

Sincerely,

Michelle Séguin on behalf of:

The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
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200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

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ATIA - 19(1)

BUREAU DU CORONER

202[redacted]
Date de l'avis

[redacted]
N° de dossier

IDENTITÉ

[redacted]
Prénom à la naissance

[redacted]
Nom à la naissance

54 ans
Âge

Féminin
Sexe

[redacted]
Municipalité de résidence

[redacted]
Province

Canada
Pays

DÉCÈS

2021[redacted]
Date du décès

[redacted]
Lieu du décès

[redacted]
Municipalité du décès

ATTENDU QU'en date du 4 novembre 2021, j'ai produit un rapport d'investigation concernant le décès de Mme[redacted]

ATTENDU QU'il y a lieu de corriger deux erreurs matérielles qui se sont produites dans les sections Circonstances du décès et Analyse du rapport;

ATTENDU QU'au premier paragraphe de la section Circonstances du décès, on doit lire que la vision de Mme[redacted] se trouble, qu'elle a des nausées et des vomissements et qu'elle peine à manger le [redacted]et non le [redacted]

ATTENDU QU'au sixième paragraphe de la section Analyse, on doit lire que Mme[redacted]a eu des effets secondaires pendant 9 jours avant de se présenter aux urgences et non pendant 5 jours;

EN CONSÉQUENCE, je produis le présent rapport amendé, lequel remplace le rapport émis le 4 novembre 2021.

IDENTIFICATION DE LA PERSONNE DÉCÉDÉE

M[me] [redacted]s'est identifiée elle-même à son arrivée à [redacted]

CIRCONSTANCES DU DÉCÈS

Le [redacted]2021, Mme [redacted] et son conjoint se rendent sans rendez-vous au centre de vaccination COVID-19 de [redacted] Ils y reçoivent leur première dose du vaccin AstraZeneca contre le coronavirus SRAS-CoV-2 (COVID-19). Dès le lendemain, Mme [redacted]ressent une grande fatigue et des maux de tête, avec des périodes où elle va mieux. Le [redacted]sa vision se trouble, elle a des nausées et vomissements et peine à manger. Elle se rend à l'urgence de [redacted]vers 18 h le [redacted] Divers tests et bilans sont effectués. Le test coronavirus express COVID-19 ressort négatif. Le bilan sanguin démontre, entre autres, une glycémie élevée et une thrombocytopénie (diminution du nombre de plaquettes sanguines qui sont alors de 11 x 10^9 thrombocytes/L alors que les valeurs de référence sont entre 137-374 x 10^9 thrombocytes/L). Des examens d'imagerie révèlent une thrombose veineuse aiguë extensive de tous les sinus veineux intracrânien majeurs avec un possible début d'hémorragie sous arachnoïdienne secondaire à une obstruction du drainage veineux. Étant donné la nature

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de sa condition, Mme [redacted] est transférée dans un état stable à [redacted] pendant la nuit.

À l'admission à [redacted] aux petites heures du [redacted] Mme [redacted] montre des signes de dysphasie (trouble du langage), d'état confusionnel, d'hypertension et d'hyperglycémie. Des immunoglobines intraveineuses (IgIV) et un anticoagulant sont administrés, mais la condition neurologique continue de se détériorer. Une thrombectomie veineuse est alors effectuée et son état s'améliore, Mme [redacted] est consciente, alerte, orientée et stable.

Le [redacted] une légère faiblesse du bras gauche est observée.

Au matin du [redacted] son état se détériore subitement, elle doit être intubée. Des examens d'imagerie révèlent un important saignement intracrânien frontal gauche avec signe d'hypertension intracrânienne. Une craniotomie est pratiquée d'urgence pour réduire la pression intracrânienne. Des antibiotiques et deux unités de plaquettes sanguines sont donnés, car elle était sous anticoagulants.

Les [redacted] Mme [redacted] démontre des signes de dommages neurologiques irréversibles, son pronostic de récupération est très sombre. Après discussion avec la famille, des soins de confort sont donnés et les traitements de maintien des fonctions vitales sont retirés. Elle décède peu après. Le décès est constaté le [redacted] 2021 à [redacted]

EXAMEN EXTERNE, AUTOPSIE ET ANALYSES TOXICOLOGIQUES

Comme les lésions et conditions qui ont entraîné le décès de Mme [redacted] sont bien documentées dans son dossier médical de [redacted] aucune expertise additionnelle n'a été ordonnée.

ANALYSE

Le dossier médical indique que Mme [redacted] souffrait de diabète de type 2 pour lequel elle devait prendre deux médicaments par voie orale. Elle avait subi une cholécystectomie (ablation de la vésicule biliaire) et une néphrectomie droite (ablation du rein droit) dans le passé. Les examens d'imagerie de contrôle datant de 2019 ne révélaient rien d'inquiétant. Une échographie abdominale datant de la même époque notait une stéatose hépatique importante. Aucun malaise n'avait été mentionné lors du dernier suivi médical effectué par téléphone en janvier 2021. Des intolérances ou allergies alimentaires (pêche, pois, pomme, noix) et médicamenteuses (amoxicilline, héparine) sont notés au dossier médical.

Selon le ministère [redacted] la thrombocytopénie immunitaire prothrombotique induite par l'administration du vaccin (TIPIV ou TTIV) demeure un effet secondaire rare. Elle peut se produire dans les 4 à 20 jours suivants l'administration de vaccins à vecteur viral (AstraZeneca ou Covishield) contre la COVID-19. Au moment d'écrire ce rapport, seulement huit cas de TTIV avaient été recensés au [redacted] sur 563,806 doses de vaccin AstraZeneca administrées contre la COVID-19 (un neuvième cas de TTIV est lié au vaccin Covishield). Mme [redacted] est la seule personne qui malheureusement en est décédée.

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Les symptômes de TTIV sont : maux de tête graves et/ou persistants, symptômes neurologiques focaux (incluant vision trouble), convulsions, difficulté à parler, essoufflement, douleur à la poitrine, enflure et rougeur d'un membre, douleur abdominale persistante, membre froid ou pâle, présence de contusions (bleus) sur la peau. Plus de cas sont rapportés concernant des femmes de moins de 55 ans, mais il est possible que les femmes soient surreprésentées selon les stratégies de vaccination utilisées par les différents pays. En date du 15 juillet 2021, au [redacted] le taux de TTIV à la suite des vaccins à vecteur viral (AstraZeneca et Covishield) contre la COVID-19 était de 1,3/100 000 doses administrées. Tous les cas déclarés sont survenus après la première dose.

Il n'y a présentement aucune indication claire sur la prédisposition de certains patients à la TTIV. Il est donc impossible de déterminer si les conditions médicales préexistantes de Mme [redacted] (diabète, organes manquants, intolérances ou allergies alimentaires et médicamenteuses) augmentaient ses risques de TTIV.

Par mesure de précaution, le [redacted] avait annoncé le [redacted] 2021 que le vaccin AstraZeneca (et le Covishield) ne serait plus administré aux personnes de moins de 55 ans, jusqu'à nouvel ordre. Or, je note que Mme [redacted] qui avait 54 ans, a quand même été vaccinée avec ce vaccin douze jours après cette date. Je me suis questionnée sur l'efficacité du moyen de communication utilisé par le [redacted] Le [redacted] m'a confirmé que l'avis du Comité sur l'immunisation avait été envoyé sous embargo par courriel à tous les responsables provinciaux et coordonnateurs en maladies infectieuses et qu'un communiqué avait été émis le [redacted] 2021. Deux jours après, les recommandations étaient intégrées au Protocole d'immunisation [redacted] qui est la norme de pratique professionnelle pour tous les vaccinateurs [redacted] Tous les abonnés à l'infolettre du Protocole d'immunisation [redacted] ont été avisés de cette mise à jour le [redacted] avril, une précision a été envoyée par la [redacted] concernant l'année de naissance pour l'administration de ce vaccin. Le [redacted] le Comité sur l'immunisation recommandait que les vaccins à vecteur viral soient désormais offerts aux personnes de 45 ans et plus, car les avantages de la vaccination dépassaient largement les risques de TTIV. Il m'apparait donc que le MSSS avait mis en place un moyen efficace de communication de l'information et que la vaccination de Mme [redacted] pendant la « pause » alors qu'elle était à la limite de l'âge permise n'est pas un élément déterminant dans son décès.

Puisque Mme [redacted] a eu des effets secondaires pendant neuf jours avant de se présenter aux urgences, je me suis demandé si les personnes qui se faisaient vacciner étaient suffisamment informées des effets secondaires des différents vaccins et du moment où il était crucial pour elles de se rendre aux urgences. On m'a informée que le 10 mars 2021, suite à l'homologation du vaccin AstraZeneca, une feuille d'information spécifique à ce vaccin avait été produite et mise à jour le 31 mars afin d'ajouter des précisions sur le risque de thrombose. Le 30 mars 2021, le [redacted] a également mis en ligne et diffusé aux associations professionnelles ainsi qu'à ses partenaires un document d'information concernant la TTIV. Il semble donc que l'information était disponible et que Mme [redacted] se soit présentée aux urgences quand elle a commencé à ressentir les symptômes sévères décrits dans l'information disponible.

Un test mesurant la présence d'anticorps dirigés contre le facteur plaquettaire 4 (PF4) effectué le [redacted] 2021 a permis de confirmer que Mme [redacted] avait effectivement eu une TTIV.

À la lumière du dossier médical et de l'information reçue du [redacted] je conclus que Mme [redacted] a subi une TTIV consécutivement à l'administration du vaccin AstraZeneca qui a causé une hémorragie intracrânienne dont elle est décédée.

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CONCLUSION

Mme [redacted] est décédée d'une hémorragie intracrânienne secondaire à une thrombocytopénie immunitaire prothrombotique induite par l'administration du vaccin (TTIV) AstraZeneca contre la COVID-19. Il s'agit d'un décès accidentel.

Je soussignée, coroner, reconnais que la date indiquée, et les lieux, les causes, les circonstances décrits ci-dessus ont été établis au meilleur de ma connaissance, et ce, à la suite de mon investigation, en foi de quoi j'ai signé, à [redacted] ce [redacted] 2021.

[redacted]

Me [redacted] coroner

Page: 1,328 of/de 2,140
A2023000085

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ATIA - 19(1)

Bureau du coroner

[redacted]

Rapport d'investigation du coroner

[redacted]

[redacted]

concernant le décès de

[redacted]

Me [redacted]

[redacted]

ATIA - 19(1)

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From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
To: 14186436174@fax.hc-sc.gc.ca
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: RE: Suivi par Santé Canada - Vaccin COVID-19 Astra Zeneca
Date: 2021-12-01 11:20:58 AM

Chère Me. [redacted] coroner,

Merci pour la déclaration d'un effet secondaire suivant l'immunisation (ESSI). Par conséquent de suivi d'évaluation par Santé Canada, le Programme de Canada Vigilance (PVC) a identifié cette déclaration pour un suivi.

L'information que vous avez fournie dans votre déclaration a été enregistrée dans la base de données du Programme Canada Vigilance sous le numéro de déclaration d'effet indésirable (DEI) 000977087.

Informations supplémentaires sur les EI après la vaccination par le vaccin COVID-19
Pour votre information, Santé Canada (SC) et l'Agence de la santé publique du Canada (ASPC) se partagent la surveillance de la sécurité des vaccins au Canada. Pour en savoir plus, veuillez consulter la page Web Déclaration des effets secondaires suivant l'immunisation (ESSI) au Canada (https://www.canada.ca/fr/sante-publique/services/immunisation/declaration-manifestations-cliniques-inhabituelles-suite-immunisation/formulaire.html).

SC et l'ASPC collaborent étroitement pour surveiller les rapports d'événements indésirables suivant l'immunisation avec les vaccins COVID-19 au Canada par le biais du PVC et du Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI). Les ESSI sont surveillés de façon régulière. Le gouvernement du Canada publie chaque semaine des informations sur les ESSI avec les vaccins COVID-19 (https://sante-infobase.canada.ca/covid-19/securite-vaccins/).

Canada Vigilance No	**Clarification**
000977087 (Date de réception [Santé Canada]): 24/11/2021 Vaccin COVID-19 Astra Zeneca	Veuillez SVP donnez toute information supplémentaire concernant: Comme l' Agence de la santé publique du Canada examine également ce cas et étant donné qu'en raison de la loi sur la protection des renseignements personnels, nous ne sommes pas en mesure de partager les résultats de votre enquête (incluant l'information liée à l'identité du patient ou du déclarant), pouvons-nous vous demander de **svp transmettre ce rapport à votre autorité sanitaire locale** [redacted] afin que l'ASPC complète son évaluation de causalité. (L'autorité locale de santé publique, à son tour fera rapport par l'intermédiaire des autorités fédérales, provinciales ou territoriales chargées de l'immunisation. Les ESSI sont finalement transmises à l'ASPC).

Votre action dans les meilleurs délais serait grandement apprécié pour l'évaluation de ce cas.

Si vous avez besoins de plus d'informations, n'hésitez pas à me contacter.

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Merci de votre collaboration,

Michelle Séguin

Le Programme Canada Vigilance, Santé Canada

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
michelle.seguin@canada.ca

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ATIA - 19(1)

FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQU'IL EST REMPLI

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
71 ans ____ mois	☑ Homme ☐ Femme	____ cm 5 pi 4 po	____ kg 130 lbs ____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

greffe rein (2018) et rejet aigu (2020) [cardiopathie hypertensive] parkinson 2018 resolue (2019)

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]		

4. Adresse [redacted]

5. Courriel [redacted]

6. Langue préférée

☑ français
☐ anglais

7. Organisation (le cas échéant) [redacted]

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ☐ Médecin ☐ Pharmacien
☑ Autre professionnel de la santé (spécifier) : infirmière

9. Cela a-t-il été déclaré au fabricant? Oui

☑ Oui ☐ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire*

☑ Décès (fournir la date) entre le [redacted] 2021
☐ Met la vie en danger
☐ Hospitalisation
☐ Prolongation d'une hospitalisation
☐ Incapacité
☐ Malformation congénitale
☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

☐ Oui ☑ Non ☐ Inconnu
☐ En cours de rétablissement (expliquer) :

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

vaccin bras gauche le [redacted] 2021 le lendemain, zona ⊕ syndrome paraneoplasique tumeur bras gauche. Depuis, diminution de l'état général, ralentissement psycho-moteur et décès le

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
vaccin COVID	0,5ml	Moderna

4. N° du lot	5. N° du DIN / N° du NPN
3001176	

6. Pays d'achat
☐ Canada
☐ États-Unis
☐ Autre (spécifier) : ____

7. Où le produit a-t-il été acheté/obtenu?
☑ Pharmacie [redacted]
☐ Épicerie
☐ Internet
☐ Autre (spéci[redacted]

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021-[redacted]	2021[redacted]

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
	1X	IM

13. Pourquoi le produit a-t-il été pris/prescrit?*

prévention COVID

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?
☑ Oui
☐ Non

15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☑ Oui Zona ↓ progressivement
☐ Non
☐ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?
☐ Oui
☑ Non
☐ Ne s'applique pas

17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui
☐ Non
☑ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire
☐ Certain
☑ Probablement/vraisemblablement
☐ Possiblement
☐ Pas disponible / incapable de vérifier
☐ Improbable
☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

prise de médication, mais prise de longue date

20. Tests/données de laboratoire pertinents

Health Canada / Santé Canada
DEC 15 2021
[illegible]

Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada

Pub : 150143 | Date : avril 2020

Santé Canada Health Canada

Canada

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Le déclarant est [redacted] infirmière permis: [redacted]

Mais la personne affectée est [redacted]

Mère: [redacted]

M a reçu le vaccin COVID-19 Moderna lot 3001176 le 2021-[redacted] au à la pharmacie [redacted] # [redacted] au matin deltoïde gauche, par inf. [redacted]

1 journée plus tard pour 48h. ne s'est presque pas alimenté, léthargie, douleur MSG puis oedème +++ tout le bras ad doigts gauche, difficulté à bouger. M hospitalisé du 2021-[redacted] au 2021-[redacted] à l'hôpital [redacted] Zona ⊕ syndrome parsonage turner diagnostiqué. M a reçu valacyclovir traitement.

M a reçu services du [redacted] soutien à domicile tous les jours pour aide à l'habillage, car incapable de s'habiller pose soins de plaies pour écoulements +++ MSG, pansement a été fait rég quelques mois. Etat général s'est progressivement dégradé. Selon vaisin, depuis hospit m a vu son état général se dégrader.

Le [redacted] 2021, m n'était plus capable de se lever, je l'ai donc fait hospitaliser, puis m est décédé quelques jours plus tard. Le [redacted] on m'a avisé qu'il était décédé

M était suivi à la clinique des greffes rénal de l'hôpital [redacted]

Dx: greffe rénal (2018) c rejet aigu (2020), parkinson,

Il faudrait appeler sa pharmacie pour avoir profil médicament datant du jour où a eu son vaccin. Voici une liste ~~des~~ qui peut donner une idée des médicaments pris.

[redacted] 2021-12-06.

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[redacted]

PROFIL MEDICAL

[redacted]

No Dossier [redacted]
Nom: [redacted]
Naissance : [redacted] (71 ans) Sexe: M

Allergies: aucune allergie connue
Intolér./RIM:

Ordonnances	Dates	Durée TX
VALACYCLOVIR 500 mg/co. (VALTREX) 500 MG = 1 CO(s) par la bouche, 2 FOIS PAR JOUR x 1 mois (Du [redacted] 2021)	Début: 2021 Fin: 2021	J6
TINZAparine 3500 unités/ 0.35 mL ser. inj. (INNOHEP) 3500 UNITÉ = 0.35 ML sous-cutané, AUX 24 HEURES	Début: 2021 Fin:	J6
ATORVASTATINE 10 mg/co. (LIPITOR) 20 MG = 2 CO(s) par la bouche, AU COUCHER	Début: 2021 Fin:	J6
HydrALAZINE 25 mg/co. (APRESOLINE) 25 MG = 1 CO(s) par la bouche, AUX 8 HEURES AU BESOIN si TA > 150/90	Début: 2021 Fin:	J5
CARVEDILOL 12.5 mg/co. (COREG) 37.5 MG = 3 CO(s) par la bouche, 2 FOIS PAR JOUR	Début: 2021 Fin:	J6
AMLOdipine 5 mg/co. (NORVASC) 5 MG = 1 CO(s) par la bouche, AU COUCHER	Début: 2021 Fin:	J5
ACETAMINOPHENE 325 mg/capl. * (TYLENOL) 650 MG = 2 CO(s) par la bouche, AUX 4 HEURES AU BESOIN	Début: 2021 Fin:	J6
PREgabaline 25 mg/caps. (LYRICA) 25 MG = 1 CAP(s) par la bouche, 2 FOIS PAR JOUR	Début: 2021 Fin:	J5
LEVODOPA+BENSERAZIDE 50-12,5 mg/caps. (PROLOPA) 4 CAP(s) par la bouche, 3 FOIS PAR JOUR	Début: 2021 Fin:	J6
CALCIUM CARBONATE 500 mg (Ca++) /co. (OSCAL) 500 MG = 1 CO(s) par la bouche, 1 FOIS PAR JOUR	Début: 2021 Fin:	J6
MAGNESIUM COMPLEXE 250 mg Mg élém. / co. (MAGNESIUM JAMIESON) 500 MG = 2 CO(s) par la bouche, 2 FOIS PAR JOUR	Début: 2021 Fin:	J5
PANTOPRAZOLE 40 mg/co. (PANTOLOC) 40 MG = 1 CO(s) par la bouche, 1 FOIS PAR JOUR	Début: 2021 Fin:	J6
PrednISONE 5 mg/co. (PREDNISONE) 7.5 MG = 1 1/2 CO(s) par la bouche, 1 FOIS PAR JOUR	Début: 2021 Fin:	J6
VITAMINE D3 (ALFACALCIDOL) 0.25 mcg/caps. (ONE ALPHA) 0.25 MCG = 1 CAP(s) par la bouche, AU COUCHER	Début: 2021 Fin:	J6
Tacrolimus *ADVAgraf* 3 mg/caps. L.A. (ADVAGRAF) 3 MG = 1 CAP(s) par la bouche, LE MATIN Ce médicament s'administre toujours DIE, à la même heure	Début: 2021 Fin:	J6

Imprimé le : 2021-05-04 - 07:45

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ATIA - 19(1)

Nom du patient : N° dossier :

Imp (suite):

vs

2) Névrite herpétique au zona nerf radial

vs

Atteinte médullaire 2nd à myélome? moins probable
vs polyneuropathie moins probable

Conduite: - EMG MSG
- IRM cervical

Tableau complexe de Faiblesse progressive MSG et Allodynie et Oedème important MSG : A noter que note du [redacted] documentait une 6 Force a/n MSG
Cliniquement : Faiblesse MSG distale > proximale à une hyporéflexie relative MSG en considérant hyperréflexie diffuse (à noter que ~~[illegible]~~ avait eu une IRM cervicale en 2019 pour une hyperréflexie).

Hypothèse : localisation Plexus brachial gauche
vs Mononeuropathie multiple ⊖ probable
vs Radiculaire multiple

Etiologie ?
- Infiltratif
- Compressif Une atteinte médullaire n'est pas exclut mais le pattern des ROT est en défaveur (mais doute sur niveau sensitif C4).
* Se pourrait-il qu'une atteinte axillaire du plexus et structure environnante pourrait expliquer lymphoedème?

Plan: 1) Reprise
Acyclovir IV par prudence ?

2) IRM Plexus en FDS et cervical

3) Selon IRM : +/- PL
+/- EMG (mais sera limité à cause oedème)

Disponible à microbio.
Vu tx déjà entamé et encore sur valtrex.
Confirmons dx et tx selon évolution
↑ évolution de façon anormale

	2021	[redacted]
Heure	Année	Mois J[redacted] Nom et signature du médecin traitant (N° de permis)

NE RIEN ÉCRIRE DANS LES MARGES

NE RIEN ÉCRIRE DANS LES MARGES

2016-07-22 2 de 2

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ATIA - 19(1)

Seguin, Michelle (HC/SC)

From: Seguin, Michelle (HC/SC)
Sent: 2023-01-13 2:24 PM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: Suivi par Santé Canada - Vaccin COVID-19 Spikevax (Moderna)

Chère Mme. [redacted]

Merci pour la déclaration d'un effet secondaire suivant l'immunisation (ESSI). Par conséquent de suivi d'évaluation par Santé Canada, le Programme de Canada Vigilance (PVC) a identifié cette déclaration pour un suivi.

L'information que vous avez fournie dans votre déclaration a été enregistrée dans la base de données du Programme Canada Vigilance sous le numéro de déclaration d'effet indésirable (DEI) 000980575.

Informations supplémentaires sur les EI après la vaccination par le vaccin COVID-19

Pour votre information, Santé Canada (SC) et l'Agence de la santé publique du Canada (ASPC) se partagent la surveillance de la sécurité des vaccins au Canada. Pour en savoir plus, veuillez consulter la page Web Déclaration des effets secondaires suivant l'immunisation (ESSI) au Canada

SC et l'ASPC collaborent étroitement pour surveiller les rapports d'événements indésirables suivant l'immunisation avec les vaccins COVID-19 au Canada par le biais du PVC et du Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI). Les ESSI sont surveillés de façon régulière. Le gouvernement du Canada publie chaque semaine des informations sur les ESSI avec les vaccins COVID-19.
Pour nous aider dans nos activités de surveillance, veuillez nous envoyer les informations de suivi ci-dessous (si disponibles) :

Canada Vigilance No	Clarification
000980575 Date de réception [Santé Canada]: 15 décembre 2021 Vaccin COVID-19 Spikevax (Moderna)	Veuillez SVP donnez toute information supplémentaire concernant: Est-ce que c'est possible que vous avez aussi transmis une déclaration ***initial*** le ***22 juillet 2021***? L'écriture nous semble identique mais dans la section B « renseignements sur le déclarant », l'information du patient [redacted] est fourni.

Votre action dans les meilleurs délais serait grandement apprécié pour l'évaluation de ce cas.

Si vous avez besoins de plus d'informations, n'hésitez pas à me contacter.

Merci de votre collaboration,

Michelle Séguin

Le Programme Canada Vigilance, Santé Canada

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ATIA - 19(1)

Seguin, Michelle (HC/SC)

From: [redacted]
Sent: 2023-01-13 5:14 PM
To: Seguin, Michelle (HC/SC)
Subject: Re: Suivi par Santé Canada - Vaccin COVID-19 Spikevax (Moderna)

Oui , il s'agit de la même personne. Je l ai accompagné lorsqu'il l a déclaré. Je n étais pas certaine que sa déclaration ait été envoyé.

N'hésitez pas si vous avez d autres questions

[redacted]

Le ven. 13 janv. 2023 à 14:23, Seguin, Michelle (HC/SC) <michelle.seguin@hc-sc.gc.ca> a écrit :

Chère Mme. [redacted]

Merci pour la déclaration d'un effet secondaire suivant l'immunisation (ESSI). Par conséquent de suivi d'évaluation par Santé Canada, le Programme de Canada Vigilance (PVC) a identifié cette déclaration pour un suivi.

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Canada Vigilance No	Clarification
000980575 Date de réception [Santé Canada]: 15 décembre 2021 Vaccin COVID-19 Spikevax (Moderna)	Veuillez SVP donnez toute information supplémentaire concernant: Est-ce que c'est possible que vous avez aussi transmis une déclaration ***initial*** le ***22 juillet 2021***? L'écriture nous semble identique mais dans la section B « renseignements sur le déclarant », l'information du patient (JYB) est fourni.

Votre action dans les meilleurs délais serait grandement apprécié pour l'évaluation de ce cas.

Si vous avez besoins de plus d'informations, n'hésitez pas à me contacter.

Merci de votre collaboration,

Michelle Séguin

Le Programme Canada Vigilance, Santé Canada

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
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ATIA - 19(1)

Canada Vigilance AER#:	000981762 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211224 CCYYMMDD
	HC Initial Received Date:	20211224 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR-20211224115124_222643()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
		Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Community -

Patient (B.1)

Patient Initial (B.1.1) [redacted]	Sex (B.1.5) Male	Patient height (B.1.4)	Patient weight (B.1.3)
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2) 73 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1) 2021[redacted] CCYYMMDD	Was autopsy done? (B.1.9.3) Yes

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ATIA - 19(1)

Canada Vigilance AER#:	000981762 (0)	Page#2

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.3 ml		
Dosage text (B.4.k.6)		
30 MCG / 0.3 ML IM frequencytext:1x		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
6 Days	6 Days	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) AMLODIPINE	
Active Substance names (B.4.k.2.2) amlodipine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) CICLESONIDE	
Active Substance names (B.4.k.2.2) ciclesonide		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) DULOXETINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) duloxetine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ROSUVASTATIN	
Active Substance names (B.4.k.2.2) rosuvastatin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Subcutaneous	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) BAKTAR	
Active Substance names (B.4.k.2.2) sulfamethoxazole-trimethoprim		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) CALCIUM CARBONATE CO	
Active Substance names (B.4.k.2.2) calcium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN D3 1000 IU TABLETS	
Active Substance names (B.4.k.2.2) vitamin d		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 80006935 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FERROUS GLUCONATE	
Active Substance names (B.4.k.2.2) iron		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FOLIC ACID	
Active Substance names (B.4.k.2.2) folic acid		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	SALBUTAMOL	
Active Substance names (B.4.k.2.2)		
salbutamol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

AUTOIMMUNE HEMOLYTIC ANEMIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Autoimmune hemolytic anemia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Autoimmune haemolytic anaemia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	3 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
6 Days	6 Days	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

STROKE

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Stroke
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

JAUNDICE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Jaundice
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Jaundice

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MULTISYSTEM ORGAN FAILURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Multi organ failure
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Multiple organ dysfunction syndrome

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LIVER FAILURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Liver failure
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Hepatic failure

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

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Canada Vigilance AER#:	000981762 (0)	Page#14

The patient presented to [redacted] Hospital, [redacted] on 2021[redacted] with autoimmune hemolytic anemia 6 days post the third dose of COVID-19 vaccine; side effect previously occurred on prior dose and was treated successfully. This time, the patient progressed to severe symptoms and was diagnosed clinically with stroke. Patient died shortly thereafter. An autopsy was performed at [redacted] Hospital (under standing contract for [redacted] to cover LH adult autopsies), and confirmed massive jaundice and findings consistent with multisystem organ failure. No specific acute brain event was evident to sufficiently explain death. Death is preliminarily attributed to complications of the autoimmune hemolytic anemia, itself likely a side effect of the vaccine.

Most responsible physician believed to be Mc[redacted] CPSO# [redacted] Spoke with Dr. [redacted] briefly and he is aware the event is being reported.

Dhpr log details:
Safety Report ID: CA-DHPR-20211224115124_222643
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20211224
First Name: [redacted]
Last Name:
Telephone:
Ext.:
Address:
City:
Province/Territory:
Postal Code:
Email address:
Organization:
Reporter Type: Physician

Patient ID: [redacted]
Age: 73 Year(s)
Sex: Male
Height:
Weight:
Med History: Idiopathic warm autoimmune hemolytic anemia, likely idiopathic, s/p prednisone taper with good response, in remission
Diffuse large B-cell lymphoma, remote, s/p chemotherapy, deemed cured

Allergies:

Serious Death: Yes
Date of Death: 2021[redacted]
Serious Life-Threatening: Yes
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other: Yes
Serious Other Explain: Presented with autoimmune hemolytic anemia 6 days after receiving COVID-19 vaccine, having had a similar reaction to a prior dose.

Reaction 1
Outcome: Died
Reaction Start Date: 2021[redacted]
Reaction End Date: 2021[redacted]
Reaction Description: Patient experienced autoimmune hemolytic anemia, likely liver failure, and multisystem organ failure, resulting in death. Had received COVID-19 vaccine on 2021[redacted] Autopsy confirmed findings in keeping with this on 2021[redacted]

Suspect Product 1
DIN #/NPN #: 02509210
Product Name: COMIRNATY - PREVIOUSLY/AUPARAVANT - PFIZER-BIONTECH COVID-19 VACCINE
Strength:
Strength other:
Dosage form: 30 MCG / 0.3 ML IM
Manufacturer: PFIZER-BIONTECH
Lot #:
Expiry date:
Product start date: 2021[redacted]
Product end date: 2021[redacted]
Dose: 30 MCG / 0.3 ML IM
Frequency: 1x
Route of administration: Intramuscular
Route of administration - Other:
Indication: Vaccine
Reported to Mfr: No
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Not applicable
Dechallenge: N/A
Rechallenge: N/A

Concomitants: amlodipine 5 mg daily, ciclesonide 50 mcg nasal spray daily, duloxetine 90 mg daily, rosuvastatin 20 daily, sulfamethoxazole-trimethoprim (800-160 mg 3x per week), calcium carbonate 500 mg daily, vitamin D3 2000 U daily, ferroua gluconate 300 mg 3x/week, folic acid 5 mg daily, salbutamol inhaler as needed
Test/Lab results narrative: Autopsy: death, preliminarily attributed to a complication of COVID-19 vaccine

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Autoimmune hemolytic anemia		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diffuse large B-cell lymphoma	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chemotherapy	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Idiopathic warm autoimmune hemolytic anemia, likely idiopathic, s/p prednisone taper with good response, in remission
Diffuse large B-cell lymphoma, remote, s/p chemotherapy, deemed cured

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

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Canada Vigilance AER#:	000981762 (0)	Page#16

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
Dr.	[redacted]		[redacted]
Reporter organization (A.2.1.2a) [redacted]		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) [redacted]			
Reporter city (A.2.1.2d) [redacted]		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f) [redacted]	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Canada Vigilance AER#:	000981762 (0)	
Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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From: Uy, Justine (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2022-01-19 12:54 PM
To: Eng, Kathleen (HC/SC); Lavigne, Andree-Anne (HC/SC); Jawad, Aasha (HC/SC)
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC); Seguin, Michelle (HC/SC); Uy, Justine (HC/SC)
Subject: FW: [External] RE: Health Canada Follow-Up / Clarification Request
Attachments: PH Hx.pdf

Good afternoon,

Please see attached for the response to the follow up request concerning: 000981762.

@Aasha, can you please attach/track this follow-up accordingly to the report?

Thank you,
Justine

From: [redacted]
Sent: 2022-01-17 3:05 PM
To: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <canada.vigilance.covid19vaccine-vaccincovid19@hc-sc.gc.ca>
Cc: michelle.seguin@canada.ca
Subject: RE: [External] RE: Health Canada Follow-Up / Clarification Request

Please find documents I have attached. (Sorry, it has been an extremely taxing few weeks)

From: Seguin, Michelle (HC/SC) <michelle.seguin@hc-sc.gc.ca> **On Behalf Of** Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: Wednesday, December 29, 2021 2:00 PM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <canada.vigilance.covid19vaccine-vaccincovid19@hc-sc.gc.ca>
Subject: [External] RE: Health Canada Follow-Up / Clarification Request

EXTERNAL

Re: Health Canada Follow-Up Clarification Request

Good afternoon Dr. [redacted]

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We are contacting you today to thank you and to confirm receipt of the adverse event following immunization (AEFI) report initially submitted to the Canada Vigilance Program on **December 24th, 2021** regarding suspect product: **COMIRNATY (Pfizer-BioNTech) COVID-19 VACCINE**.

As the result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified the present individual case safety reports (ICSRs) where clarification is needed in order to complete the case evaluation.

Canada Vigilance Case Number	**Clarification Requested**
000981762	To further assess this report it would be helpful to have the following information: • Confirmation of date and vaccine for 2 prior COVID vaccine doses • Confirmation of autoimmune hemolytic anemia following prior dose of COVID vaccine (medical confirmation, date of onset following vaccination, laboratory confirmation, clinical status etc.), treatment and evidence of full recuperation • Patient past medical history (over and above what was provided, if applicable: Idiopathic warm autoimmune hemolytic anemia, likely idiopathic, s/p prednisone taper with good response, in remission Diffuse large B-cell lymphoma, remote, s/p chemotherapy, deemed cured) • Confirmation of medications, indications and duration of medications if available (reported concomitants were: amlodipine 5 mg daily, ciclesonide 50 mcg nasal spray daily, duloxetine 90 mg daily, rosuvastatin 20 daily, sulfamethoxazole-trimethoprim (800-160 mg 3x per week), calcium carbonate 500 mg daily, vitamin D3 2000 U daily, ferrous gluconate 300 mg 3x/week, folic acid 5 mg daily, salbutamol inhaler as needed)

May you please kindly respond to both myself, Michelle Séguin: michelle.seguin@canada.ca in addition to the Canada Vigilance COVID-19 Vaccine generic account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca).

Or, if you prefer, you may fax the requested information to the **Canada Vigilance Program fax at 1-866-678-6789;** please cite case number 000981762.

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If you require further information within the scope of this request, please do not hesitate to contact me.

We thank you once again for your time.

Sincerely,

Michelle Séguin
The Canada Vigilance Program, Health Canada

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
michelle.seguin@canada.ca

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(1) Follow any unsubscribe process the sender has included in their email
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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Consultation Report [redacted] 2021 17:3[redacted]
Provider [redacted] **Status: Final**

Consultation Report

[redacted]

CONSULTATION REPORT

Patient: [redacted]
MRN: [redacted] DOB: [redacted] 1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted]

IDENTIFYING INFORMATION:
[redacted] is a 72-year-old gentleman whom I saw in person today in the [redacted] 2021. He was referred to Hematology by Dr. [redacted] his family doctor, for a new onset of macrocytic anemia, query MDS. [redacted] is actually Dr [redacted] as he is a family doctor and has been for many years.

PAST MEDICAL HISTORY:
1. Diffuse large B-cell lymphoma in 2003 - I do not have the formal pathology but some notes in our metastatic suggest that it may have been a T-cell rich diffuse large B-cell lymphoma. He was treated with R-CHOP at that time, actually on a clinical trial in 2003 at [redacted] It looks like he went into complete response and has been in remission ever since.
2. Allergic rhinitis.
3. Asthma.
4. Eczema.
5. Hypertension.
6. Left bundle branch block.
7. Carotid stenosis.
8. BPH.
9. Osteopenia.
10. Left medial meniscal tear.
11. Patellofemoral syndrome, left knee.
12. Cervical spondylosis
13. Degenerative disc disease.
14. Low testosterone.
15. Previous cystitis.
16. Remote rib fractures.
17. Tonsillectomy.
18. Cataract.

MEDICATION(S):
1. Amlodipine 5 mg p.o. daily.

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[redacted] DOB [redacted] 1948 (73y) Male HCN: [redacted]

Consultation Report - [redacted] 2021 17:34 [redacted]
Provider: [redacted] **Status: Final**

2. Calcium 500 mg p.o. daily.
3. Duloxetine 90 mg p.o. at bedtime.
4. Crestor 20 mg p.o. daily.
5. Ventolin 2 puffs inhaled p.r.n.
6. Vitamin D 1000 units p.o. daily.

ALLERGIES:
There is a previously documented allergy to PERINDOPRIL.

***** [redacted] Reported by: [redacted]
***** Unique [redacted]

SOCIAL HISTORY:
Dr. [redacted] lives with his family in [redacted] He drinks about two alcoholic beverages per day. He is a nonsmoker. As mentioned, he is a family physician and does not have private drug coverage.

HISTORY OF PRESENT ILLNESS:
Essentially, Dr. [redacted] describes having shortness of breath on exertion as well as fatigue over the past month. He says this came about relatively acutely and prior to that he has been overall feeling well. He says at rest he is doing fine. He denies any symptoms of jaundice, scleral icterus, dark urine or pale stools. He denies any constitutional symptoms. No fevers, chills, night sweats or weight loss. He has no new lymphadenopathy anywhere on the body. He denies any chest pain.

PHYSICAL EXAMINATION:
On examination today, Dr. [redacted] looks quite well. His weight today is 73 kilos. Temperature is 37.2, heart rate 90, blood pressure 155/84, O2 sat 97% on room air. Cardiac exam shows a slight systolic murmur and normal S1, S2. Respiratory exam shows good air entry bilaterally with no adventitious sounds. Abdominal exam shows a soft, nontender abdomen with no palpable organomegaly. There is no palpable lymphadenopathy in the head and neck, axillary or inguinal areas. Dr. [redacted] looks pale to the examination, but not overtly jaundiced and there is no overt scleral icterus.

INVESTIGATION(S):
Blood work from the outside lab prior to his assessment showed a hemoglobin of 88 with an elevated MCV at 109 and the referral was made for a query MDS. Previous hemoglobins from a couple of years back were completely normal in the 130s.

Looking at his blood work from today, his hemoglobin is a bit improved at 101. MCV still elevated at 107.5. White count is normal at 4, platelets normal 284, neutrophils normal at 3.3. Retic count is elevated today at 191. Ferritin is normal at 115. B12 is 192, creatinine 112 with a creatinine clearance of 44. His calcium is 2.2, total bilirubin slightly elevated at 24 and LDH is elevated at 393. Based on the initial CBC which showed elevated reticulocytes as opposed

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Page: 1,360 of/de 2,140
A2023000085
Date: 02 Jan 2022 07:17

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to low reticulocyte, I did ask for further testing to rule out hemolysis. I added on a haptoglobin, which at the moment is still pending as well as a direct antiglobulin test.

ASSESSMENT AND PLAN:
Dr. [redacted] is a 72-year-old gentleman with macrocytic anemia in the context of a previous lymphoma over 15 years ago, treated with chemotherapy. He has been in remission ever since. The question I was asked about a new macrocytic anemia and whether it could be related to MDS.

I discussed things with Dr. [redacted] today and showed him his blood work. Overall, based on the clinical history, MDS would be a reasonable suspicion, however, the fact that the reticulocyte count is elevated, it does not correlate with that. I do wonder, in fact, if there is actually a hemolysis that is going on here given that there is an elevated reticulocyte count, there is an elevated LDH and a slightly elevated total bilirubin. Certainly, the confirmatory test would be the

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

haptoglobin and the direct antiglobulin test, which are still pending. Overall, I think at this point the most prudent thing is for us to wait for the results of these tests and then decide how to proceed from there. I described that if this was hemolysis, the most common cause is something called warm autoimmune hemolytic anemia. I described that in most cases this is idiopathic, but can sometimes be brought on by other conditions like lymphomas or other malignancies. The initial treatment for this is usually with prednisone as well as nutritional supplements.

If this is indeed MDS, I would say that it is most likely to be a low risk for MDS. The reason I say this is because the other counts, the white blood cell count and platelet count are completely normal. Dr. [redacted] seems to have been spending a lot of time thinking about whether this was MDS and did ask about other things like treatments including things like stem cell transplant. I did describe that whereas yes these are potential treatments for MDS, at this point there is really no confirmation at all that, that is what he has and it is probably safest to approach things one at a time. He understood this and was happy to wait for further investigations. At this point, I will plan to call Dr. [redacted] later on this week once they have confirmatory investigations. I may have some result even later this evening and can touch base with him at that point. If this is hemolytic anemia, I will call him and likely prescribe him a course of prednisone as well as other supportive medications. If the hemolytic anemia investigations are negative, then we will have another discussion about proceeding forward with a bone marrow biopsy, probably in short fashion in the next week or two.

Thank you for allowing me to participate in the care of Dr. [redacted] His questions were all answered to his satisfaction and I will plan to

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Page: 1,361 of/de 2,140
A2023000085
Date: 02 Jan 2022 07:17

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN** [redacted]

Consultation Report - [redacted] 2021 17:34 [redacted]
Provider [redacted] **Status: Final**

follow up with him later this week over the phone.

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]
DD: [redacted]/2021 17:34:45 PM
DT: [redacted]/2021 20:38:07 PM
RT: [redacted]/2021 20:38:07 PM
RPT ID: [redacted]

cc: [redacted]

^^^

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Date: 02 Jan 2022 07:17

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Progress Report - [redacted] 2021 16:03 ([redacted]
Provider: [redacted] **Status: Final**

Progress Report

[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted]/1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted], 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021.

DIAGNOSIS(ES):
Warm autoimmune hemolytic anemia - likely idiopathic with no known secondary cause. Presented with hemoglobin in the 80s to 100. To start prednisone.

INTERVAL HISTORY:
[redacted] is a 72-year-old gentleman with whom I spoke to over the phone today, [redacted] 2021. I last saw him in-person earlier this week as a first consultation for anemia. At that time, he was referred by Dr. [redacted] for consideration of MDS due to his previous history of lymphoma, treated with chemotherapy. Today, I spoke to [redacted] over the phone due to the risk of COVID-19. We discussed the risks and benefits of telephone assessment including the lack of physical examination, as well as the need for him to seek in-person medical attention if necessary. [redacted] understood this, was able to give consent today.

Since I last spoke to [redacted] overall he has continued to be well. It seems like he did still have quite a bit of anxiety with regards to the potential of this being a diagnosis of MDS, which is a hematologic malignancy and does significantly affect his overall prognosis and duration of life span. Overall, he says his energy levels are stable. He has not noticed any signs or symptoms of bleeding and denies any chest pain or shortness of breath.

PHYSICAL EXAMINATION:
Deferred as this is a telephone assessment.

INVESTIGATION(S):
I have results of all the blood work that was previously pending from his last visit. Essentially, at that time, his hemoglobin was low at 101 and his LDH was elevated at 393. I can now confirm that his

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[redacted] DOB: [redacted] 1948 (73y) Male HCN: [redacted]

Progress Report - [redacted] 2021 16:03 [redacted]
Provider [redacted] **Status: Final**

haptoglobin was undetectable and a direct antiglobulin test or the Coombs test was positive for IgG coding the red blood cells. This confirms a diagnosis of warm autoimmune hemolytic anemia.

ASSESSMENT AND PLAN:
Dr. [redacted] is a 72-year-old gentleman with a new diagnosis of warm autoimmune hemolytic anemia. At this point, there is no clear secondary source and is suspected to be idiopathic.

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

[redacted] and I had a long discussion about the diagnosis, as well as the treatment going forward. I described that warm autoimmune hemolytic anemia is an immune mediated phenomenon, which leads to immune mediated destruction of the red blood cells. The treatment of this in the acute setting is with a high dose of prednisone to control the immune system and control the hemolysis. As well, I have prescribed the patient a variety of medications to help with managing the potential side effects of prednisone as well as medications to active hematinics to help with red blood cell production. Essentially for [redacted] this will consist of a starting dose of prednisone 75 mg daily for two weeks, which is 1 mg/kg with his weight around 73 kilograms. With regards to supportive medications, I have sent prescriptions to his pharmacy for Tecta 40 mg daily for stomach prevention, increased his calcium and vitamin D to 1000 mg of calcium daily and vitamin D 2000 units daily, as well as sent a prescription to his pharmacy for Septra-DS 1 tablet Monday, Wednesday, Friday for PJP prophylaxis. I described the other side effects of steroids could include increased appetite, weight gain, fluid retention, anxiety, agitation, and insomnia. [redacted] being a physician knew most of this already. Other prescription I gave him today were for maintaining his red blood cell building blocks such as a prescription for vitamin B12, folic acid, as well as ferrous gluconate.

Overall, [redacted] was quite happy to hear that this did turn out to be hemolytic anemia as opposed to MDS. I did describe to him that often hemolytic anemia like this does respond to a prolonged taper of steroids, but there is always a chance similar to another hematologic condition like ITP that it may relapse in the future.

My plan for [redacted] is to follow up with him in two weeks with some repeat blood work. He knows if he does notice any significant drop in energy level or any significant side effects to either call my office or go directly to the emergency department if it is felt to be severe.

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

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ATIA - 19(1)

[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

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Progress Report - [redacted] 2021 16:03 [redacted]
Provider [redacted] **Status: Final**

[redacted]
DD: [redacted]/2021 16:03:40 PM
DT: [redacted]/2021 04:05:45 AM
RT: [redacted]/2021 04:05:45 AM
RPT ID: [redacted]

cc: [redacted]

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User Id: [redacted] *Organization* [redacted]
Date: 02 Jan 2022 07:18

Page: 1,365 of/de 2,140
A2023000085

ATIA - 19(1)

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[redacted] **DOB** [redacted] 1948 (73y) Male **HCN** [redacted]

Progress Report - [redacted] 2021 14:50 [redacted]
Provider: [redacted] **Status: Amended (A)**

Progress Report
[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted] 1948, Sex: M
HCN: [redacted]
Acct # [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021.

DIAGNOSIS(ES):
Warm autoimmune hemolytic anemia - likely idiopathic with no known secondary cause. Presented with hemoglobin in the 80s to 100s. Started prednisone 75 mg daily about 7 to 10 days ago. Previous history of a diffuse large B-cell lymphoma in 2003 treated with chemotherapy in remission ever since.

INTERVAL HISTORY:
Dr. [redacted] is a 72-year-old gentleman with whom I spoke to over the phone today, [redacted] 2021. I last spoke to him a couple of weeks ago and once again we spoke over the phone due to the risks of COVID in [redacted] and once again he gave consent.

[redacted] does describe a bit of a delay in obtaining the prednisone to start for his anemia. The reason is because he was actually trying to get his shingles vaccination before then and he has done. Apart from that, [redacted] does note that more recently since starting prednisone, he has noticed sweating in the nighttime. He says that these do occasionally require him to wake up in the middle of the night and to switch his sheets or specifically to put a towel over his sheets to control the sweating. He says that this may have been present a little bit before starting prednisone, but it is very noticeable now. Apart from that, he denies any fevers, chills, weight loss or lymphadenopathy. His sleep is overall sustained, but still a little bit disturbed by prednisone. Energy level seems steady and he denies any chest pain or shortness of breath. He has not had any recent signs or symptoms of bleeding.

PHYSICAL EXAMINATION;
Deferred as this is a telephone assessment.

INVESTIGATION(S):

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Date: 02 Jan 2022 07:19

ATIA - 19(1)

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Progress Report - [redacted] 2021 14:50 [redacted]
Provider [redacted] **Status: Amended (A)**

[redacted]s most recent lab work shows no improvement in his hemoglobin as of yet. His hemoglobin is still steady at 98. Last time I saw him, it was 101. White count 5.8, platelet count 334, both normal. Retic count is elevated at 232, as it would be expected and MCV is still high at 110. LDH is 272 still elevated, however, now total bilirubin and haptoglobin have normalized. Creatinine is 97.

ASSESSMENT AND PLAN:
[redacted] is a 72-year-old gentleman with warm autoimmune hemolytic

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

anemia on prednisone 75 mg daily, which is 1 mg/kg. He has had only about 8 or 9 days of prednisone so far and his hemoglobin still has not yet improved. I described to him that I want to see at least some improvement in his hemoglobin before starting to taper prednisone, so I did give him another prescription for 75 mg daily to go forward. I will plan to see him again in 2 weeks to recheck his blood work and hopefully by that time he has had some response. He does have some good signs in that his haptoglobin and bilirubin are normal and hopefully in 2 weeks the hemoglobin will have improved as well. As well, he will continue on with his other prophylactic medications as we had started previously.

With regards to the night sweats again this does seem to be temporally related to the steroids. Given, however, there is a previous history of lymphoma and the fact that now there is a new warm autoimmune hemolytic anemia and rarely this is secondary to lymphoproliferative disorder. I will organize CT scans of the neck, chest, abdomen and pelvis to rule out any malignancy here.

Thank you for allowing me to participate in Dr. [redacted] care. I will plan to follow up with him in a couple of weeks.

2D

[redacted] M.D.

[redacted]
DD: [redacted]/2021 14:50:28 PM
DT: [redacted]/2021 06:57:19 AM
RT: [redacted]/2021 06:57:19 AM
RPT ID: [redacted]

cc: [redacted]

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Date: 02 Jan 2022 07:19

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Progress Report - [redacted] 2021 14:50 [redacted]
Provider: [redacted] **Status: Amended (A)**

========== END OF DOCUMENT / CHANGE LOG FOLLOWS ==========

Elec. Signed By
[redacted] M.D.
on [redacted]-2021 08:53 ET

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Date: 02 Jan 2022 07:19

ATIA - 19(1)

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN** [redacted]

Progress Report - [redacted] 2021 13:30 [redacted]
Provider: [redacted] **Status: Final**

Progress Report

[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted] /1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted], M.D.

DATE OF CLINIC:
[redacted] 2021.

DIAGNOSIS(ES):
Warm autoimmune hemolytic anemia - likely idiopathic. Presented with hemoglobin in 80s to 100. Started prednisone 75 mg daily and has been on it for about three to four weeks. Hemoglobin is starting to respond. Plan for long prednisone taper. Previous history of diffuse large B-cell lymphoma in 2003 treated with chemotherapy, in remission since.

INTERVAL HISTORY:
Dr. [redacted] is a 72-year-old gentleman with whom I spoke to over the phone today, [redacted] 2021. As previous, we spoke as a phone appointment due to the risk of COVID in [redacted] and once again he gave consent.

Overall, [redacted] continues to do reasonably well on the high dose prednisone. He says that he feels somewhat of a hypomania that actually seems like it gives him more energy, but otherwise seems to have tolerated the prednisone reasonably well. He has not had a significant weight gain or sleep disruption as yet. He denies any fevers, chills, night sweats or weight loss recently; however, he did complain about some night sweats previously. We do have a CAT scan that was ordered that is still pending about that. As I mentioned in a previous note, Dr. [redacted] has had his first dose of the COVID vaccine previously and is due for his next dose next month. He has not noticed any jaundice, dark urine or pale stools.

PHYSICAL EXAMINATION:
Deferred as this is a telephone assessment.

INVESTIGATIONS:
His most recent blood work shows an improvement in his hemoglobin up to 118, previously was 98. White count 8.4, platelet count 252, MCV 103, retic count 91. Total bilirubin 12, LDH 250. Haptoglobin 1.57.

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Date: 02 Jan 2022 07:20

ATIA - 19(1)

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l'information

[redacted] DOB: [redacted] 1948 (73y) Male HCN [redacted]

Progress Report - [redacted] 2021 13:30 [redacted]
Provider [redacted] **Status: Final**

Essentially, this suggests that the hemolysis is minimal at this point, LDH is still elevated, but all the other hemolytic markers are normal. He still has some degree of MCV increase with normal retic count.

ASSESSMENT AND PLAN:
[redacted]Hoy is a 72-year-old gentleman with a warm autoimmune hemolytic anemia. He has had a good jump in his hemoglobin and now I think it is safe for us to decrease his prednisone and start the taper. I will be doing a taper of 50 mg for one week, 40 mg for one week, 30 mg for one

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

week, 20 mg for one week, 15 mg for one week, 10 mg for one week, 5 mg for one week, and then he can stop. I will continue to ask him to do his blood work every two weeks for the time being. As well, he will continue on with all his prophylactic medications.

There is still a CT scan that is pending, which is due to happen in the next week and I will follow up on that. I will plan to speak to Dr. [redacted] again over the phone in about four weeks to review the next couple of rounds of his blood work.
Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]
DD: [redacted]/2021 13:30:21 PM
DT: [redacted]/2021 07:29:42 AM
RT: [redacted]/2021 07:29:42 AM
RPT ID: [redacted]

cc: [redacted]

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[redacted] DOB [redacted] 1948 (73y) Male HCN: [redacted]

Progress Report - [redacted] 2021 19:17 [redacted]
Provider [redacted] Status: Final

Progress Report
[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted] 1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021

DIAGNOSIS(ES):
Warm autoimmune hemolytic anemia - likely idiopathic. Presented with hemoglobin in 80s to 100. Started prednisone 75 mg daily, and now on taper with good response. Previous history of diffuse large B-cell lymphoma in 2002 through 2003, treated with chemotherapy, in remission.

INTERVAL HISTORY:
Dr. [redacted] is a 72-year-old gentleman with whom I spoke with today, [redacted] 2021. As previous, we spoke as a phone assessment due to the risk of COVID in Ontario and once again he gave consent.

Overall, [redacted] continues to do reasonably well. He has actually had been a bit easier in the last few weeks as his prednisone continues to taper down as he has not had as much trouble with the sweats that he was struggling with earlier on. In general, he just feels better. He does confide in me the significant stress of his work as he has had to work very hard, especially recently during his illness.

Physical examination was deferred as this is a telephone assessment.

INVESTIGATION(S):
[redacted]'s most recent blood work shows a hemoglobin of 120, white count 8.6, platelet count 299. LDH is still mildly elevated at 300, but bilirubin is 9 and haptoglobin is 1.45 completely normal. Retic was only mildly elevated at 108.

ASSESSMENT AND PLAN:
Dr. [redacted] is a 72-year-old gentleman with warm autoimmune hemolytic anemia. He has had a good response to prednisone and his hemolysis is minimal at this point. He is currently on 20 mg of prednisone and will continue tapering down. He should be completed his taper in about 4

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weeks' time. I will plan to follow up with his blood work a couple of weeks after he has completed the taper just to see where things have leveled off.

I should mention that [redacted] did recently have a CT scan of the chest, abdomen and pelvis to look for any recurrence of lymphoma or other explanation for his hemolytic anemia. Reassuringly, the CT scan only identifies the small node in the axilla that was known from previous that has been unchanged in size, ever since 2003. There is no other

***** [redacted] Reported by: [redacted]
***** Unique [redacted]

suggestion of malignancy. [redacted] was very happy to hear that. I will plan to follow up with him over the phone after he has completed his prednisone.

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]
DD: [redacted]/2021 19:17:35 PM
DT: [redacted]/2021 04:14:33 AM
RT: [redacted]/2021 04:14:33 AM
RPT ID: [redacted]

cc: [redacted]

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Progress Report - [redacted] 2021 17:18 [redacted]
Provider [redacted] **Status: Final**

Progress Report

[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted] 1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021.

FAMILY PHYSICIAN:
Dr. [redacted]

DIAGNOSIS(ES):
Warm autoimmune hemolytic anemia, likely idiopathic. Presented with hemoglobin in 80s to 100s. Started prednisone 1 mg/kg and has now tapered off. Initially a good response, but hemoglobin has dropped again after completing therapy. Previous history of diffuse large B-cell lymphoma, treated remotely with chemotherapy, essentially cured.

INTERVAL HISTORY:
Dr. [redacted] is a 72-year-old gentleman with whom I spoke with over the phone today, [redacted], 2021. I last reviewed him just about a month ago. I did try to get a hold of him last week to review his blood work, however, I was unable to reach him on the phone. [redacted] was away that day and did see my message that I left. Once again, we spoke over the phone due to the risks of COVID in [redacted] and once again he gave consent.

Since I last spoke to him, [redacted] does note that his energy level seems to have dropped to touch. It is not as bad as it was prior to when he first saw me, but he says he has had a perceptible change. On top of that, he still is having a lot of difficulty with his excessive workload and I think this is probably contributing as well. He completed his steroids just about a week or two ago.

Physical examination was deferred as this is a telephone assessment.

INVESTIGATION(S):
[redacted] s hemoglobin has dropped to 99, compared to the last time I saw him, which was 120. White count is 4.8, platelet count 286. His hemolytic markers have also slightly risen with LDH up to 397,

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Date: 02 Jan 2022 07:21

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[redacted] DOB [redacted] 1948 (73y) Male HCN: [redacted]

Progress Report - [redacted] 2021 17:18 [redacted]
Provider [redacted] Status: Final

previously was 300. Haptoglobin as well is now undetectable. Essentially, Paul is having recurrent hemolysis.

ASSESSMENT AND PLAN:
Dr. [redacted] is a 72-year-old gentleman with warm autoimmune hemolytic anemia. Unfortunately, it seems as though his disease has recurred after completing his prednisone taper. I will plan to bring him into the hospital next week to follow up in person and repeat some blood work and likely it may be that we do need to restart some kind of therapy at

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

that time. It may be a long-term consideration as well to do a bone marrow to rule out any underlying MDS. Even when his hemoglobins were well controlled, he was not able to get up higher than about 120. Again, the clear etiology here still is his autoimmune hemolytic anemia. [redacted] is happy with this plan and will see me next week.

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]
DD: [redacted]/2021 17:18:10 PM
DT: [redacted]/2021 03:20:15 AM
RT: [redacted]/2021 03:20:15 AM
RPT ID: [redacted]

cc: [redacted]

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Progress Report - [redacted] 2021 11:20 [redacted]
Provider: [redacted] **Status: Final**

Progress Report

[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN [redacted] DOB: [redacted]/1948, Sex: M
HCN [redacted]
Acct #:
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021.

FAMILY PHYSICIAN:
Dr. [redacted]

DIAGNOSIS(ES):
1. Warm autoimmune hemolytic anemia, likely idiopathic. Presented with hemoglobin in 80s to 100. Started prednisone 1 mg/kg and now tapered off. Initially had good response, but hemoglobin has dropped again after completing therapy with ongoing positive hemolytic markers.
2. Previous history of diffuse large B-cell lymphoma, treated remotely with chemotherapy, essentially cured.

INTERVAL HISTORY:
Dr. [redacted] is a 72-year-old gentleman whom I saw in person today in the [redacted] on [redacted] 2021. I last spoke to him on the phone a week ago. I want to bring him back into the hospital because he was having a hemoglobin drop since discontinuing prednisone. Overall, [redacted] says he does still note that his energy is lower, but not as bad as when he was first diagnosed. He particularly notes shortness of breath with exertion going up stairs and things like that. He has not noticed any dark urine or pale stools. He has not had any signs or symptoms of bleeding. He tolerated steroids reasonably well with no overt side effects, but again he was quite happy to finish them.

PHYSICAL EXAMINATION:
On examination today, Dr. [redacted] looks reasonably well. His weight is 72.2 kg, temperature 36.8, heart rate 76, blood pressure 147/80, O2 sat 99% on room air. Cardiac and respiratory exams are within normal limits.

INVESTIGATION(S):
His blood work today shows a white count 4.7, hemoglobin 109 and platelet count 316. Hemoglobin actually has gone up 10 points since his

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Date: 02 Jan 2022 07:21

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[redacted] DOB [redacted] 1948 (73y) Male HCN [redacted]

Progress Report [redacted] 2021 11:20 [redacted]
Provider [redacted] Status: Final

outside lab work when his hemoglobin was 99. He still has elevated retic count of 158, as well as elevated LDH of 384 and undetectable haptoglobin at less than 0.1 in keeping with ongoing active hemolysis. His bilirubin was not elevated. Creatinine is 105. Ferritin 86 and B12 at 269.

His DAT continues to be positive at 3+.

ASSESSMENT AND PLAN:

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

[redacted] is a 72-year-old gentleman with warm autoimmune hemolytic anemia. He did complete steroids and was on treatment for just over three months before tapering off. Unfortunately, since tapering off, [redacted]'s hemoglobin has gone down again. In the last week, he has rebounded a little bit, but there is clear presence of ongoing hemolysis.

I had a long discussion with him today about what to do going forward. Essentially, he is still having active hemolysis. The prednisone seemed to have worked for the time being, but it may have been that we tapered off a little bit too quickly. Sometimes it is even recommended that people are on a long taper of six months or so. Again, sometimes I try to avoid this just to spare the patient's side effects of steroids, but it may be that something longer like this is needed. As well, there is also a potential need for using a secondary medication as well as steroids as a bit of a steroid-sparing agent, something like azathioprine, cyclophosphamide or cyclosporine. I did print off a research paper about treatment options for patients with hemolytic anemia and did give it to [redacted] The other option here is for something like rituximab, which has been well studied in hemolytic anemia. Unfortunately, it is not covered. I will inquire about it with our drug access facilitator to see if there is any compassionate access or at least what the cost would be if he were to pay out of pocket. Unfortunately, Dr. [redacted] does not have a private medical insurance.

Again, at the moment with [redacted]s recent rebound in hemoglobin, I think the most reasonable thing is to just watch and wait and observe him for the time being. I want to repeat his blood work in a couple of weeks. If the blood work continues to be stable or continues to improve, it may be that we can withhold therapy for a little while. If the hemoglobin does drop down again, specifically if it goes below 100 or 90, then I do think we need to reintervene with immunosuppressive therapy. [redacted] understands this.

Thank you for allowing me to participate in the care of Dr. [redacted] I will plan to follow up with him in a couple of weeks' time.

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN** [redacted]

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Progress Report - [redacted] 2021 11:20 [redacted]

Provider [redacted] **Status: Final**

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]

DD: [redacted]/2021 11:20:43 AM
DT: [redacted]/2021 12:06:59 PM
RT: [redacted]/2021 12:06:59 PM
RPT ID: [redacted]

cc: [redacted]

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN** [redacted]

Progress Report - [redacted] 2021 16:47 [redacted]
Provider [redacted] **Status: Final**

Progress Report

[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted] /1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021

DIAGNOSIS(ES):
1. Warm autoimmune hemolytic anemia, likely idiopathic. Presented with hemoglobin in the 80s to 100. Started prednisone 1 mg/kg and tapered off over a course of about 3 months. He had good response with hemoglobin slightly dropping after treatment. Ongoing mild hemolysis, on surveillance.
2. Previous history of diffuse large B-cell lymphoma, treated remotely with chemotherapy, essentially cured.

INTERVAL HISTORY:
Dr. [redacted] is a 72-year-old gentleman with whom I spoke with over the phone today on [redacted] 2021. I last reviewed him a couple of weeks ago. At that time, I brought him in person to recheck his blood work. [redacted] has had blood work again in the last couple of days and once again we spoke on the phone due to risk of COVID in [redacted] and as previously he was able to give consent.

Overall, Dr. [redacted] says that he has been feeling reasonably similar to how he had been before. His energy level seems to be stable. He has not noticed any recent signs or symptoms of bleeding. There is no jaundice, dark urine or pale stools. His energy level has been stable since previous. Last time we spoke, we did look into other options as a second-line agent for warm autoimmune hemolytic anemia such as rituximab.

Physical examination was deferred as this is a telephone assessment.

INVESTIGATION(S):
Most recent hemoglobin is actually slightly improved from previous now up to 113. When I last saw him, it was 109, white count 3.5, platelet count of 260. MCV is 107, still elevated and retic count is borderline

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A2023000085
Date: 02 Jan 2022 07:23

elevated as well as 109. Haptoglobin is actually normal now at 0.3, although LDH is still elevated at 293. Total bilirubin is also normal at 9. Creatinine 88. Essentially, his LDH and haptoglobin have been improved from previous, although he continues to have some ongoing hemolysis. The extent of it has actually decreased from previous.

ASSESSMENT AND PLAN:
[redacted] is a 72-year-old gentleman with warm autoimmune hemolytic anemia. He has completely tapered off prednisone and although he

***** HOY,DR [redacted] Reported by: [redacted]
***** Unique # [redacted]

continues to have some hemolysis. His hemoglobin has been reasonably stable in the last little while. Unfortunately, hemoglobin has not completely normalized. He still has significant macrocytosis even with only a mild reticulocytosis at this point, so there may still be an underlying diagnosis of myelodysplastic syndrome II. Right now, although [redacted] is relatively asymptomatic and the hemoglobins are reasonable. At this point, I think we should continue on with just observation. I plan for possibly blood work in a month and I will plan to call him in followup after that. If things continue to be stable, then we can continue on with followup bit more spread out. If unfortunately the hemoglobin does drop and he has had further relapse of his hemolysis, then we will need to think about second-line options for repeating steroid. [redacted] understands this and is happy with the plan.

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]
DD: [redacted]/2021 16:47:26 PM
DT: [redacted]/2021 09:17:13 AM
RT: [redacted]/2021 09:17:13 AM
RPT ID: [redacted]

cc: [redacted]

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User Id: [redacted] *Organization:* [redacted]

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Progress Report - [redacted] 2021 15:24 [redacted]
Provider: [redacted] **Status: Final**

Progress Report

[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted] 1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021

DIAGNOSIS(ES):
1. Warm autoimmune hemolytic anemia, likely idiopathic. Treated with long-term prednisone taper over 3 months with a good response to treatment. Currently, no evidence of active hemolysis.
2. Previous history of diffuse large B-cell lymphoma treated remotely with chemotherapy, essentially cured.

INTERVAL HISTORY:
Dr. [redacted] is a 72-year-old gentleman with whom I spoke with over the phone today, [redacted] 2021. Once again, we spoke over the phone due to the risks of COVID in [redacted] and as previously gave consent. Since we last spoke, [redacted] has been reasonably stable. Unfortunately, just around the time we have last spoke [redacted] has got a diagnosis of shingles. It was quite painful and did cause him a bit of trouble at that time, but fortunately, things seemed to have resolved from that point. His energy levels are overall stable and he still feels tired, but again his practice is very exhausting for him. He has not noticed any chest pain or shortness of breath and no signs or symptoms of bleeding. There is no jaundice, dark urine or pale stools.

Physical examination was deferred again as this is a telephone assessment.

INVESTIGATION(S):
His most recent blood work actually shows a significant improvement in his hemoglobin up from 113 to 130, white count of 4.5, platelets 216. Neutrophils 3.16. As well, his hemolytic markers have now normalized with bilirubin 6, LDH 214 and haptoglobin 1.25.

ASSESSMENT AND PLAN:
Dr. [redacted] is a 72-year-old gentleman with warm autoimmune hemolytic

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User Id: [redacted] *Organization:* [redacted]

ATIA - 19(1)

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Progress Report - [redacted] 2021 15:24 [redacted]
Provider [redacted] **Status: Final**

anemia. He is currently on observation and his hemoglobin and hemolytic parameters have significantly improved in the last month with no specific treatment. Again, we do see fluctuations like this sometimes or even delayed responses to prednisone, sometimes it is not very common. Again, previously his shingles or active viral infection may have contributed to further hemolysis previously, and now that has resolved. He has been stabilized a bit more. I am quite happy to see this result and as we were considering second line options for his warm autoimmune hemolytic anemia if he were to relapse again. At the moment,

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

I think we can safely put this on the back burner. For the time being, I do think it is reasonable that we continue on with a monthly blood work, but for now I will just follow up with him in 3 months' time. If there are any significant abnormalities in the blood work that was done, I will contact him of course for earlier followup.

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]
DD: [redacted]/2021 15:24:49 PM
DT: [redacted]/2021 09:07:01 AM
RT: [redacted]/2021 09:07:01 AM
RPT ID: [redacted]

cc: [redacted]

^^^

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User Id: [redacted] *Organization:* [redacted]

ATIA - 19(1)

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[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN** [redacted]

Progress Report - 29 Nov 2021 17:15 [redacted]
Provider: [redacted] **Status: Final**

Progress Report

[redacted]

ONCOLOGY NOTE

Patient: [redacted]
MRN: [redacted] DOB: [redacted] 1948, Sex: M
HCN: [redacted]
Acct #: [redacted]
Site: [redacted] Location: [redacted]
Date of Service: [redacted] 2021
Reported By: [redacted] M.D.

DATE OF CLINIC:
[redacted] 2021

FAMILY PHYSICIAN:
Dr. [redacted]

DIAGNOSIS(ES):
1. Warm autoimmune hemolytic anemia, likely idiopathic. Treated with long-term prednisone taper over 3 months with a good response to treatment. Currently, no evidence of active hemolysis on observation.
2. Previous history of diffuse large B-cell lymphoma, treated remotely with chemotherapy, essentially cured.

INTERVAL HISTORY:
Dr. [redacted] is a 73-year-old gentleman with whom I spoke with over the phone today, November 29, 2021. I last reviewed him 2 months ago. Once again, we spoke over the phone due to the risks of COVID in [redacted] and as previous, Paul was able to give consent. I did confirm his identity prior to the conversation.

Since we last spoke, overall, [redacted] has been feeling okay but right now is struggling with a lot of personal stress in his family. This is likely contributing to his energy levels. Apart from that, he has actually felt quite well with no chest pain or shortness of breath. He says that he gets occasionally itchy and occasionally feels excess sweating during the daytime, but apart from that, really has no concerns. There are no symptoms of jaundice and no signs or symptoms of bleeding from any source. He has not had any infectious symptoms recently.

PHYSICAL EXAMINATION:
Deferred as this is a telephone assessment.

INVESTIGATION(S):

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Generated from [redacted]
User Id: [redacted] *Organization* [redacted]

ATIA - 19(1)

Document Released Under the Access to Information
divulgué en
l'information

[redacted] **DOB:** [redacted] 1948 (73y) Male **HCN:** [redacted]

Progress Report - [redacted] 2021 17:15 [redacted]
Provider: [redacted] **Status: Final**

[redacted] s most recent blood work shows a white count 4.7, hemoglobin 141, platelet count 155, neutrophils 3.7, bilirubin 6, LDH 222, haptoglobin 1.47. Essentially, it is all completely normal with no evidence of hemolysis.

ASSESSMENT AND PLAN:
Dr. [redacted] is a 73-year-old gentleman with a history of warm autoimmune hemolytic anemia. Right now he is in remission with his hemoglobin normal and no evidence of active hemolysis. At this point, I

***** [redacted] Reported by: [redacted]
***** Unique # [redacted]

am quite happy with how he has responded to prednisone, especially since there was a period of time when we were not sure his responses are good. I will plan to follow up with him again in about 3 to 4 months with some repeat blood work at that time. [redacted] knows that if he does have any significant drop in energy, chest pain, shortness of breath, symptoms of jaundice or other concerning symptoms that he should use that as the motivation to get blood work done as it may be that the hemoglobin is lower at that time. He understands this quite well and apart from that is happy to see me again in a few months' time.

Electronically authenticated by Dr. [redacted]

[redacted] M.D.

[redacted]
DD: [redacted]/2021 17:15:20 PM
DT: [redacted]/2021 07:14:35 AM
RT: [redacted]/2021 07:14:35 AM
RPT ID: [redacted]

cc: [redacted]

^^^

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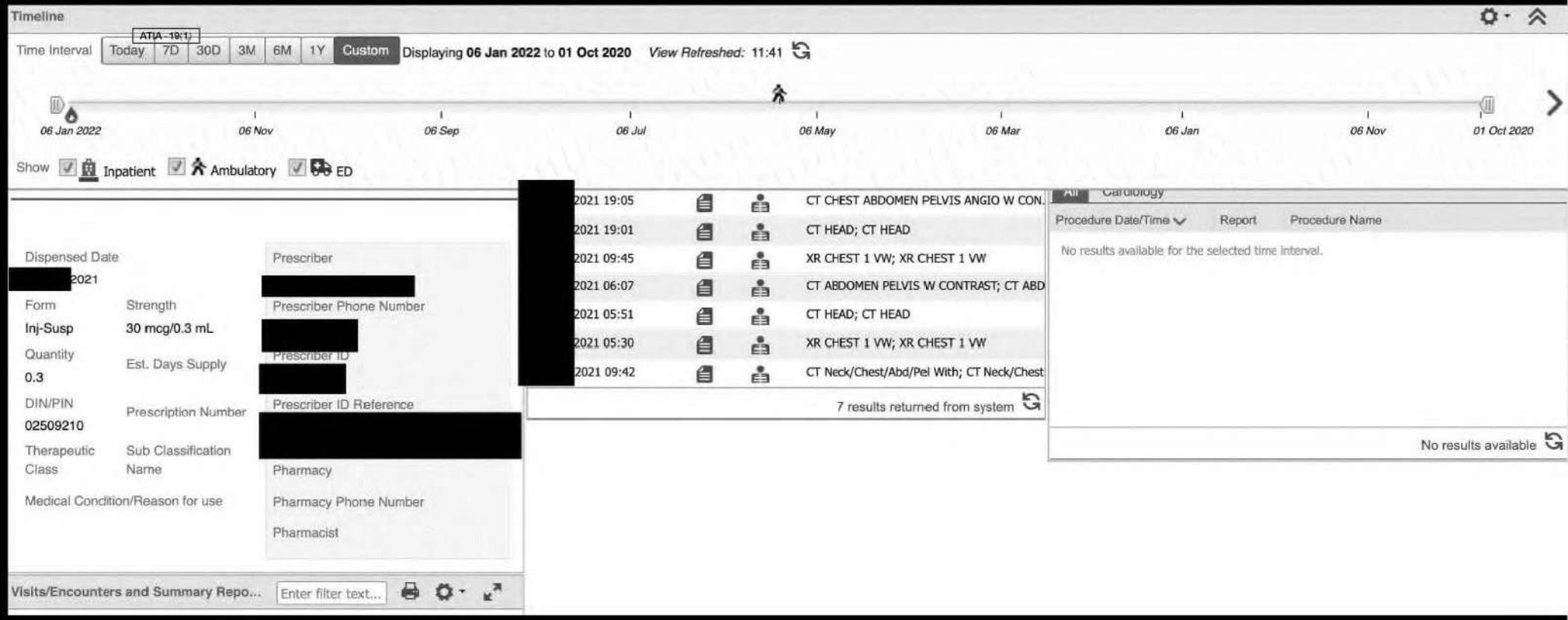
Generated from [redacted]
User Id: [redacted] *Organization:* [redacted]
Page: 1,383 of/de 2,140
A2023000085
Date: 02 Jan 2022 07:24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Show
Inpatient
Ambulatory
ED
Dispensed Date
2021
Form
Inj-Susp
Strength
30 mcg/0.3 mL
Quantity
0.3
Est. Days Supply
DIN/PIN
02509210
Prescription Number
Therapeutic Class
Sub Classification Name
Medical Condition/Reason for use
Prescriber
Prescriber Phone Number
Prescriber ID
Prescriber ID Reference
Pharmacy
Pharmacy Phone Number
Pharmacist
2021 19:05
CT CHEST ABDOMEN PELVIS ANGIO W CON
2021 19:01
CT HEAD; CT HEAD
2021 09:45
XR CHEST 1 VW; XR CHEST 1 VW
2021 06:07
CT ABDOMEN PELVIS W CONTRAST; CT ABD
2021 05:51
CT HEAD; CT HEAD
2021 05:30
XR CHEST 1 VW; XR CHEST 1 VW
2021 09:42
CT Neck/Chest/Abd/Pel With; CT Neck/Chest
7 results returned from system
All
Cardiology
Procedure Date/Time
Report
Procedure Name
No results available for the selected time interval.
No results available
Visits/Encounters and Summary Repo...
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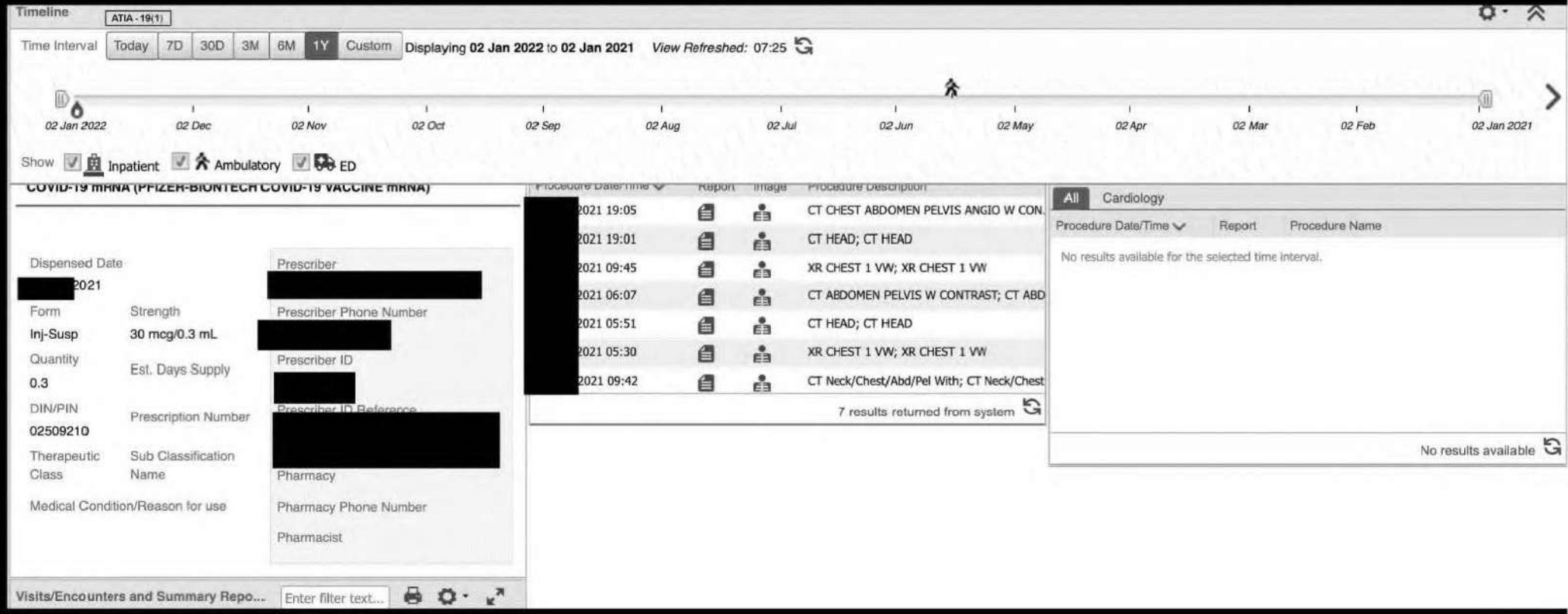
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ATIA - 19(1)
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02 Feb
02 Jan 2021
Show
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Ambulatory
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COVID-19 mRNA (PFIZER-BIONTECH COVID-19 VACCINE mRNA)
Dispensed Date
[redacted]2021
Form
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Strength
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Quantity
0.3
Est. Days Supply
DIN/PIN
02509210
Prescription Number
Therapeutic Class
Sub Classification Name
Medical Condition/Reason for use
Prescriber
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Prescriber ID
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Pharmacy
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[redacted]2021 19:01
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[redacted]2021 05:51
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Cardiology
Procedure Date/Time
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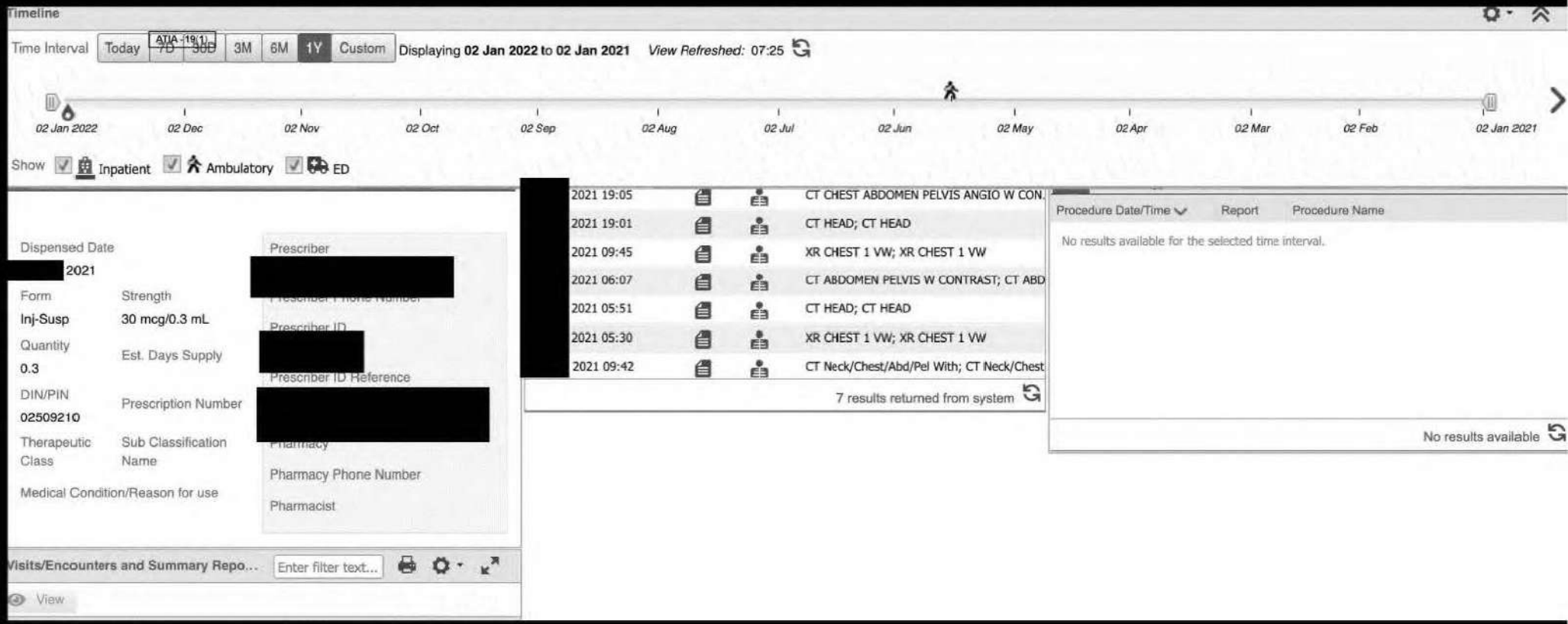
Procedure Name
No results available for the selected time interval.
No results available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02 Jan 2021
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DIN/PIN
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Therapeutic Class
Sub Classification Name
Pharmacy Phone Number
Medical Condition/Reason for use
Pharmacist
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CT Neck/Chest/Abd/Pel With; CT Neck/Chest
7 results returned from system
Procedure Date/Time
Report
Procedure Name
No results available for the selected time interval.
No results available
Visits/Encounters and Summary Repo...
Enter filter text...
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ATIA - 19(1)
Document Released Under the Access to

[redacted]

Patient Name:	[redacted]			Accession #:	[redacted]
MRN:	[redacted]	Facility:	[redacted]	Expiration date:	[redacted]2021
DOB:	[redacted]948 (Age: 73)	Location:	[redacted]	Autopsy date:	[redacted]2021
Gender:	M	Service:		Reported:	
HCN:		Visit #:	[redacted]		
Ordering MD:	[redacted] MD				

Post Mortem Hours: 7
Authorized by: [redacted]
Relationship to Patient: Wife
Autopsy Restrictions: None

Preliminary Anatomic Diagnosis

Autoimmune hemolytic anemia as an apparent complication of COVID-19 vaccine administration

[redacted]1/5/2022

Electronically verified by:
[redacted] **MD**

Major Clinical Findings
Remote history of diffuse large B-cell lymphoma treated with chemotherapy (in remission)
March 2021: First dose of COVID-19 vaccine
April-July 2021: Warm autoimmune hemolytic anemia (AIHA) [redacted]2021), treated successfully with steroid taper
[redacted]2021: Second dose of COVID-19 vaccine
[redacted]Third dose of COVID-19 vaccine
[redacted]Presented to [redacted]with dark urine, scleral icterus, and shortness of breath
Anemia (hemoglobin 99 g/L), negative direct antiglobulin test (DAT), low reticulocyte count
SARS-CoV-2 not detected by polymerase chain reaction (PCR) assay
[redacted]Increasing agitation and decreased level of consciousness
Hemoglobin level 44 g/L, transfused with 2 units of blood
Computed tomography (CT) scan of head: right middle cerebral artery (MCA) territory ischemic stroke
Not a candidate for thrombolysis due to coagulopathy and severe metabolic derangement
[redacted]Severe hyperlactemia, multisystem organ failure
Family discussion lead to redirecting goals of care to include a "do not resuscitate" (DNR) status
The patient died shortly after transition to the DNR status

Major Pathological Findings
Marked jaundice and scleral icterus
Edematous lungs (right: 980 g, left: 830 g), no masses or consolidation grossly identified
Bilateral pleural serosanguineous effusion: right 300 mL, left 300 mL
Cardiomegaly (540 g)
Pericardial serosanguineous effusion: 30 mL
Liver (1420 g): golden brown discoloration with apparent congestion, hemorrhage and possible necrosis
Spleen (350 g): diffluent and severely congested
Brain (1420 g): No external abnormalities, full evaluation by UHN Neuropathology service pending

Clinical Pathological Correlation

[redacted]

ATIA - 19(1)

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[redacted]

Autopsy Consultation Report

This 73-year-old man was diagnosed with autoimmune hemolytic anemia (AIHA) five (5) days after receiving his third dose of the COVID-19 vaccine. He had been diagnosed with AIHA in [redacted] 2021, several weeks after his first dose of the vaccine; this prior episode resolved with a three (3) month steroid taper, and the disease was not exacerbated by his second dose of the vaccine, taken during the treatment period. He received his third vaccine dose in [redacted] 2021, and experienced a rapid decline associated with AIHA starting five days after that injection, including a massive right sided ischemic stroke and multisystem organ failure. He ultimately died on [redacted] 2021.

Preliminary autopsy findings were significant for jaundice, marked splenomegaly, and hepatomegaly with apparent congestion and possible necrosis. The heart and lungs were heavy and had associated serosanguineous effusions. The external examination of the brain was unrevealing; further assessment will be performed after adequate tissue fixation. No specific acute catastrophic event to explain death was otherwise identified.

Death is attributed to AIHA likely triggered as a complication of COVID-19 vaccine. Having recently recovered from a prior episode of AIHA was likely a predisposing factor for this patient to develop AIHA again in this context. The specific mechanism of death is favored to be acute liver failure secondary to the AIHA.

THIS IS AN INTERIM REPORT ONLY. THE DIAGNOSIS GIVEN MAY BE EXTENDED OR ALTERED IN THE FINALREPORT, WHICH WILL FOLLOW.

[redacted]

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A2023000085

HC-SC REC'D 14-JA-2022
ATIA - 19(1)

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Field	
A.1 - Type of report*	Initial
A.2 - Health Canada (HC) Reference No. (for follow-up reports only)	
A.3 - Organization File No.	[redacted]
A.4 - Date report submitted	2022-01-14
A.5 - Documentation date*	[redacted]2021
A.6a - Organization contact first name*	
A.6b -Last name*	[redacted]
A.7.a - Phone no.*	[redacted]
A.7.a- ext.	
A.7.b - Email	[redacted]
A.7.c - Fax	
A.8 - Organization name*	[redacted]
A.9- Source of report (profession)	
A.10 - Heath Canada institutional ID (If ID provided, no need to provide address)	[redacted]
A.11 - Address	
A.12 - City	[redacted]
A.13 - Province/Territory	[redacted]
A.14 - Postal code	
A.15.a - Reason for seriousness: Death*	Death
A.15.a - Date of death*	
A.15.b - Reason for seriousness: Life-threatening*	
A.15.c - Reason for seriousness: Disability*	
A.15.d - Reason for seriousness: Congenital malformation*	
A.15.e - Reason for seriousness: Caused/prolonged in-patient hospitalization*	
A.15.f - Reason for seriousness: Required medical intervention to avoid any of (a) to (e)*	
B.1 - Patient ID (e.g. initials, record no.)	
B.2 - Sex**	Female
B.3.a - Age**	
B.3.b - Age unit**	53 years
B.4. Height (cm)	
B.5. Weight (kg)	

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B.6 - Known medical conditions and relevant lifestyle factors*	
B.7 - Known allergies*	
C.1 - Did the patient recover?*	<N/S>
C.2 - Reaction start date*	
C.3 - Reaction end date*	
C.4 - Description of the serious adverse drug reaction(s)**	capillary leak syndrome, compartment syndrome, rhabdo, hyperkalemia and death(also COVID positive but described post vaccine). No evidence of pneumonia
D.1 - Drug identification number (DIN)*	
D.2 - Identifying code for urgent public health need drugs (if applicable)**	
D.3 - Brand name (per product label)**	Pfizer BNT162b2
D.4 - Common/proper name (active ingredient)	
D.5 - Strength	
D.5 - Strength unit	
D.5 - Other strength unit	
D.6 - Dose	
D.6 - Dose unit	<N/S>
D.6 - Other dose unit	
D7 - Frequency	<N/S>
D.8 - Dosage form	
D.9 - Route of administration	IV
D.9 - Other route of administration	
D.10 - Product start date*	
D.11 - Product end date*	
D.12 - Indication	<N/S>
D.13 - Lot no.	
D.14 - Expiry date	
D.15.a - Manufacturer name*	
D.15.b - Did you also report to the manufacturer?	
D.15.c - Date reported	
D.15.d - Reference no. (if known)	
D.16 - What action was t aken?	<N/S>
D.17 - Did the reaction stop if dose was reduced or removed?	<N/S>
D.18 - Did the reaction return with reintroduction of the product?	<N/S>

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E - Known therapeutic products taken or used at the same time the reaction occurred*	
F.1 - Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to assessment of the serious adverse drug reaction(s).	
F.2 - "Mandatory" or "Voluntary" report	Mandatory

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ATIA - 19(1)

Lasia-Szkaradkiewicz, Bogna (HC/SC)

From: Lasia-Szkaradkiewicz, Bogna (HC/SC)
Sent: 2022-01-17 12:42 PM
To: Lasia-Szkaradkiewicz, Bogna (HC/SC)
Subject: FW: Follow up for Adverse Reaction Report # 000983841

AER# and version	**000983841 version 0.0**
Type of request	☒ Follow-up ☐ Clarification
Date first request was made	January 17, 2022
Creator of this document	Bogna Lasia-Szkaradkiewicz
Information initially requested by	☒ Creator of this document ☐ MHPD Review Bureau (provide name & Bureau): ☐ Other (provide name & contact info):
Who was contacted to obtain the information	☐ CV Quality ☐ CV Regional Office (provide name): ☐ MAH (provide name & contact info): ☒ Other (specify): [redacted] other health professional)
This request is	☒ Pending ☐ Response obtained on (provide date):

From: Lasia-Szkaradkiewicz, Bogna (HC/SC)
Sent: 2022-01-17 12:39 PM
To: [redacted]
Cc: Seguin, Michelle (HC/SC) <michelle.seguin@hc-sc.gc.ca>; Zhang, Shun (HC/SC) <shun.zhang@hc-sc.gc.ca>
Subject: Follow up for Adverse Reaction Report # 000983841

Dear [redacted]

We are contacting you with regards to suspected adverse reaction (AR) report for a 53 years old, female patient; initially submitted to the Canada Vigilance Program on January 14, 2022 and processed as a Health Canada Adverse Reaction Report # 000983841 (Reference # LRN-20220117-1495).

Based on the Health Canada assessment of the submitted information we contact you with a request for correction.

Your report indicates "IV" for the route of administration (D.9) for Pfizer BNT162b2.
Covid vaccines are administered intramuscularly. Could you clarify?
Please kindly submit your correction at your earliest convenience.

Please send your response to the Canada Vigilance Program (CVP) email at canadavigilance@hc-sc.gc.ca and copy shun.zhang@hc-sc.gc.ca, michelle.seguin@hc-sc.gc.ca and me.

Please do not hesitate to contact us if you have questions and comments.

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Best regards,
Bogna

Bogna Lasia-Szkaradkiewicz
Senior Corporate Regulatory Compliance and Enforcement Advisor
Health Canada / Government of Canada
Bogna.lasia-szkaradkiewicz@hc-sc.gc.ca / Tel: 343-542-2815

Conseiller principal ministériel de conformité et d'application de la loi,
Santé Canada / Gouvernement du Canada
Bogna.lasia-szkaradkiewicz@hc-sc.gc.ca / Tel: 343-542-2815

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ATIA - 19(1)

Seguin, Michelle (HC/SC)

From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2022-01-24 2:18 PM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: RE: Health Canada Follow-Up / Clarification Request

EXTERNAL

Re: Health Canada Follow-Up Clarification Request

Good afternoon Mrs. [redacted]

We are contacting you today to thank you and to confirm receipt of the adverse event following immunization (AEFI) report initially submitted to the Canada Vigilance Program on **January 14, 2022** regarding suspect product: **"Pfizer BNT162B2" [COMIRNATY VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION] COVID-19 Vaccine**.

As the result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified the present individual case safety reports (ICSRs) where clarification is needed in order to complete the case evaluation.

***Please note that a colleague (it would be a message deriving from "Bogna Lasia-Szkaradkiewicz, bogna.lasiaszkaradkiewicz@hc-sc.gc.ca") in training reached out to you in last week. If you could please ignore that request as it was incomplete and did not specify the generic e-mail account for COVID-19 Vaccines *** **Please consider this message as the official request from our evaluators.** We apologize for any inconvenience.

Canada Vigilance Case Number	Clarification Requested
000983841	Specifically, I would like to request the following information: • Information about the COVID-19 immunization, e.g., date of vaccination. • Relevant clinical information regarding the patient's current medical history (e.g., diabetes, smoking history, hypertension, hyper-cholesterol or hyperlipidemia and history of ischemic heart diseases, cancers) and concurrent medications. • The patient's COVID-19 infection status at the time of the adverse event. • Information about any presenting symptoms related to the adverse event. • Information about medical treatment and investigation related to the adverse events (i.e., capillary leak syndrome), e.g., blood tests (e.g., complete blood count, electrolytes, renal functions, liver functions,

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	albumin etc.) and radiological investigations (e.g., CT, MRI, angiogram, echocardiogram ultrasound, etc.). • The outcome of the Coroner investigation and the autopsy, if available.

May you please kindly respond to both myself, Michelle Séguin: michelle.seguin@canada.ca in addition to the Canada Vigilance COVID-19 Vaccine generic account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca).

Or, if you prefer, you may fax the requested information to the **Canada Vigilance Program fax at 1-866-678-6789**; please cite case number **000983841** .

If you require further information within the scope of this request, please do not hesitate to contact me.

We thank you once again for your time.

Sincerely,

Michelle Séguin
The Canada Vigilance Program, Health Canada

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Bureau du coroner

[redacted]

Rapport d'investigation du coroner

[redacted]

[redacted]

concernant le décès de

[redacted]

Me [redacted]

[redacted]

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BUREAU DU CORONER

2021[redacted]
Date de l'avis

[redacted]
N° de dossier

IDENTITÉ

[redacted]
Prénom à la naissance

[redacted]
Nom à la naissance

50 ans
Âge

Masculin
Sexe

[redacted]
Municipalité de résidence

[redacted]
Province

Canada
Pays

DÉCÈS

2021[redacted]
Date du décès

Domicile
Lieu du décès

[redacted]
Municipalité du décès

IDENTIFICATION DE LA PERSONNE DÉCÉDÉE

M.[redacted] a été identifié visuellement par un proche, sur les lieux du décès.

CIRCONSTANCES DU DÉCÈS

Le [redacted] 2021, un responsable de la coopérative d'habitation régissant l'immeuble où demeure M[redacted] se rend à son domicile. Il cogne, mais n'obtient pas de réponse. Il en informe un autre responsable. Cette personne décide de se rendre chez M.[redacted] puisqu'il ne parvient pas à le rejoindre depuis quelques jours et cela lui parait inhabituel.

Vers 20 h 5, elle cogne à son tour à la porte vigoureusement, mais en vain. Étant inquiète, elle décide de défoncer la porte. Elle entre alors dans le domicile et trouve M.[redacted] étendu sur le plancher de la cuisine, inanimé. Il contacte immédiatement le 9-1-1, alors qu'une autre personne entame des manœuvres de réanimation.

Des agents du Service de police de la[redacted] arrivent sur les lieux et poursuivent les manœuvres de réanimation jusqu'à l'arrivée des techniciens ambulanciers paramédics, quelques minutes plus tard.

À leur arrivée, les techniciens ambulanciers paramédics constatent la présence de rigidité cadavérique empêchant l'ouverture des voies respiratoires. Dans les circonstances, il est demandé au policier de cesser les manœuvres de réanimation, celles-ci étant vaines.

Le décès a été constaté à par un médecin de[redacted] à distance, selon le protocole établi, à 20 h 58.

EXAMEN EXTERNE, AUTOPSIE ET ANALYSES TOXICOLOGIQUES

Une autopsie a été faite le [redacted] 2021 à[redacted] Dans son rapport, le pathologiste a principalement décrit la présence d'une embolie pulmonaire bilatérale caractérisée par la présence d'un important caillot. La présence d'une stéatose hépatique sévère ainsi que d'athérosclérose coronarienne et aortique modérée a aussi notamment été mise en évidence. Aucune autre lésion contributive au décès n'a été observée.

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Des analyses toxicologiques ont été pratiquées au [redacted]. Aucune autre substance n'a été détectée, incluant l'alcool.

Le dépistage de la COVID-19 était négatif.

ANALYSE

Sur place, les agents n'ont observé aucun indice laissant suspecter l'intervention de tiers, aucune trace de violence ou de cambriolage.

Selon un proche, M[redacted] aurait allégué ressentir certaines difficultés respiratoires pendant la semaine précédant son décès. Il lui aurait été recommandé d'aller consulter un professionnel de la santé, ce qu'il avait refusé de faire.

Les archives médicales de M.[redacted] témoignent d'ailleurs du fait qu'il consultait très rarement des professionnels de la santé. Ses archives des quinze dernières années ne m'ont pas permis de mettre en évidence quelques antécédents médicaux pertinents.

Selon ses proches, M.[redacted] était non-fumeur et ne consommait pas d'alcool. Il était toutefois obèse et des antécédents de troubles cardiovasculaires semblent être présents dans sa famille immédiate. Bien que cela constitue des facteurs prédisposant à la formation d'un caillot sanguin pouvant entrainer une embolie pulmonaire, je ne peux faire fi du fait que M.[redacted] avait reçu la seconde dose de son vaccin contre la COVID-19 le [redacted] 2021.

L'embolie pulmonaire est l'une des rares complications possibles suivant l'admission du vaccin contre la COVID-19.

En l'absence d'évidences à l'effet qu'il s'agirait d'une embolie pulmonaire spontanée, la relation temporelle entre le vaccin et l'embolie pulmonaire bilatérale m'apparait prépondérante.

M[redacted] était actif sur les réseaux sociaux et sa dernière activité semble dater du [redacted] 2021. Une facture datée de cette journée a aussi été trouvée. Par ailleurs, le [redacted] est la date de l'anniversaire d'un membre de la famille de M.[redacted]. Or, cette personne n'a pas été contactée par M[redacted] à cette occasion ce qui est inhabituel. En considérant ces informations ainsi que l'état de conservation de son corps, j'établis la date du décès de M.[redacted] au [redacted] 2021.

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CONCLUSION

M. [redacted] est décédé d'une embolie pulmonaire bilatérale, probablement secondaire à la vaccination contre la COVID-19.

Il s'agit d'un décès accidentel.

Je soussignée, coroner, reconnais que la date indiquée, et les lieux, les causes, les circonstances décrits ci-dessus ont été établis au meilleur de ma connaissance, et ce, à la suite de mon investigation, en foi de quoi j'ai signé, à [redacted], ce [redacted] 2022.

[redacted]

Me [redacted] coroner

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HC-SC REC'D 02-AU-2022

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Field	
A.1 - Type of report*	Initial
A.2 - Health Canada (HC) Reference No. (for follow-up reports only)	
A.3 - Organization File No.	[redacted]
A.4 - Date report submitted	2022-08-02
A.5 - Documentation date*	07-04-2022
A.6a - Organization contact first name*	
A.6b -Last name*	[redacted]
A.7.a - Phone no.*	
A.7.a- ext.	
A.7.b - Email	[redacted]
A.7.c - Fax	
A.8 - Organization name*	[redacted]
A.9- Source of report (profession)	
A.10 - Heath Canada institutional ID (If ID provided, no need to provide address)	[redacted]
A.11 - Address	
A.12 - City	[redacted]
A.13 - Province/Territory	
A.14 - Postal code	
A.15.a - Reason for seriousness: Death*	Death
A.15.a - Date of death*	
A.15.b - Reason for seriousness: Life-threatening*	
A.15.c - Reason for seriousness: Disability*	
A.15.d - Reason for seriousness: Congenital malformation*	
A.15.e - Reason for seriousness: Caused/prolonged in-patient hospitalization*	
A.15.f - Reason for seriousness: Required medical intervention to avoid any of (a) to (e)*	
B.1 - Patient ID (e.g. initials, record no.)	
B.2 - Sex**	Female
B.3.a - Age**	
B.3.b - Age unit**	68 years
B.4. Height (cm)	
B.5. Weight (kg)	

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B.6 - Known medical conditions and relevant lifestyle factors*	
B.7 - Known allergies*	
C.1 - Did the patient recover?*	<N/S>
C.2 - Reaction start date*	
C.3 - Reaction end date*	
C.4 - Description of the serious adverse drug reaction(s)**	fever tachycardiaUTI
D.1 - Drug identification number (DIN)*	
D.2 - Identifying code for urgent public health need drugs (if applicable)**	
D.3 - Brand name (per product label)**	covid vaccine april 27
D.4 - Common/proper name (active ingredient)	
D.5 - Strength	
D.5 - Strength unit	
D.5 - Other strength unit	
D.6 - Dose	
D.6 - Dose unit	<N/S>
D.6 - Other dose unit	
D7 - Frequency	<N/S>
D.8 - Dosage form	
D.9 - Route of administration	<N/S>
D.9 - Other route of administration	
D.10 - Product start date*	
D.11 - Product end date*	
D.12 - Indication	<N/S>
D.13 - Lot no.	
D.14 - Expiry date	
D.15.a - Manufacturer name*	
D.15.b - Did you also report to the manufacturer?	
D.15.c - Date reported	
D.15.d - Reference no. (if known)	
D.16 - What action was t aken?	<N/S>
D.17 - Did the reaction stop if dose was reduced or removed?	<N/S>
D.18 - Did the reaction return with reintroduction of the product?	<N/S>
E - Known therapeutic products taken or used at the same time the reaction occurred*	

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F.1 - Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to assessment of the serious adverse drug reaction(s).	
F.2 - "Mandatory" or "Voluntary" report	Mandatory

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Bureau du coroner

[redacted]

Rapport d'investigation du coroner

[redacted]

[redacted]

concernant le décès de

[redacted]

Me [redacted]

[redacted]

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ATIA - 19(1)

BUREAU DU CORONER

2022[redacted]
Date de l'avis

[redacted]
N° de dossier

IDENTITÉ

[redacted]
Prénom à la naissance

[redacted]
Nom à la naissance

90 ans
Âge

Masculin
Sexe

[redacted]
Municipalité de résidence

[redacted]
Province

Canada
Pays

DÉCÈS

2022[redacted]
Date du décès

[redacted]
Municipalité du décès

Domicile
Lieu du décès

IDENTIFICATION DE LA PERSONNE DÉCÉDÉE

M[redacted] a été identifié visuellement par un membre de sa famille sur les lieux du décès.

CIRCONSTANCES DU DÉCÈS

Le [redacted] 2022 vers 13 h 30, M[redacted] reçoit un troisième vaccin contre la COVID-19. En après-midi et en soirée, il se porte bien et ne formule aucune plainte.

Le [redacted] 2022 vers 5 h, un membre de sa famille l'accompagne afin d'aller à la salle de bain. M[redacted] déclare alors avoir de la difficulté à respirer. Alors qu'il est aux toilettes, M.[redacted] ferme les yeux et semble faible. La personne accompagnant M.[redacted] va chercher un autre membre de la famille présent dans le domicile afin d'obtenir de l'aide.

Alors qu'ils arrivent auprès de M.[redacted] l'un d'eux l'entend faire deux respirations puis il cesse de respirer. Ils installent M.[redacted] au sol, contactent le 9-1-1 et entament des manœuvres de réanimation.

Des agents du Service de police de [redacted] ainsi que des techniciens ambulanciers paramédics se rendent sur les lieux. Les paramédics poursuivent les manœuvres de réanimation en vain, puisque M.[redacted] demeure en asystolie (absence d'activité électrique et cardiaque du cœur).

Le décès est par la suite constaté à distance par un médecin de[redacted] selon le protocole établi.

EXAMEN EXTERNE, AUTOPSIE ET ANALYSES TOXICOLOGIQUES

Une tomodensitométrie post mortem a été effectué[redacted]e [redacted] 2022. Dans son rapport, la radiologiste décrit la présence d'une maladie coronarienne athérosclérotique de modérée à sévère, un œdème pulmonaire et des membres inférieurs, des traces de liquide péricardique et une légère calcification de la valve aortique.

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ANALYSE

Selon ses dossiers médicaux, M. [redacted] souffrait notamment d'hypertension artérielle, d'hypercholestérolémie, de diabète et d'arthrite rhumatoïde. Une médication en lien avec ces conditions lui était d'ailleurs prescrite ainsi qu'une anticoagulothérapie.

Selon un proche, lorsque M. [redacted] avait reçu son second vaccin contre la COVID-19 en juillet 2021. Il avait ressenti des douleurs musculaires et une grande faiblesse, qui l'empêchait même de se lever, moins de 24 heures après avoir sa vaccination.

C'est en raison de cette forte réaction que des membres de la famille s'étaient assurés d'être présents auprès de M. [redacted] dans les heures qui suivraient l'administration de sa troisième dose.

La tomodensitométrie met en évidence une importante maladie coronarienne athérosclérotique ainsi qu'un œdème au niveau des poumons et des jambes. Cela est suggestif d'un tableau d'insuffisance cardiaque, lequel est aussi compatible avec le fait que peu de temps avant son décès, M. [redacted] a déclaré se sentir essoufflé.

Toutefois, ces symptômes peuvent aussi être compatibles avec une myocardite ou une péricardite, tout comme la présence de liquide péricardique qui a aussi été observée lors de la tomodensitométrie. Des cas de myocardites et de péricardites à la suite d'une immunisation contre la COVID-19 (principalement après la seconde dose du vaccin à ARNm — ce qui correspond à la vaccination reçue par M [redacted] ont d'ailleurs été rapportés dans des rapports internationaux.

Dans les circonstances, la relation temporelle entre le vaccin et l'événement cardiaque qui a entraîné le décès de M. [redacted] m'apparait prépondérante.

CONCLUSION

M [redacted] est décédé des complications d'une maladie coronarienne athérosclérotique, probablement consécutivement à la vaccination contre la COVID-19.

Il s'agit d'un décès accidentel.

Je soussignée, coroner, reconnais que la date indiquée, et les lieux, les causes, les circonstances décrits ci-dessus ont été établis au meilleur de ma connaissance, et ce, à la suite de mon investigation, en foi de quoi j'ai signé, à [redacted] ce [redacted] 2022.

[redacted]

Me [redacted] coroner

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Canada Vigilance AER#:	001024414 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20221114 CCYYMMDD
	HC Initial Received Date:	20221114 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR-20221114140147_187072()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
		Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

Community -

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male		

Date of birth (B.1.2.1)	Age group (B.1.2.3)	Onset Age (B.1.2.2)
		75 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	

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Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
covid-19 vaccine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Booster dose (3rd injection)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2022[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pneumonia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2022[redacted] CCYYMMDD	2022[redacted] CCYYMMDD	69 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MESOTHELIOMA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Mesothelioma
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Mesothelioma

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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Summary (B.5)

Case narrative (B.5.1)

null

Dhpr log details:
Safety Report ID: CA-DHPR-20221114140147_187072
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20221114
First Name: [redacted]
Last Name: [redacted]
Telephone: [redacted]
Ext.:
Address: [redacted]
City: [redacted]
Province/Territory: [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization:
Reporter Type: Consumer or other non health professional

Patient ID: [redacted]
Age: 75 Year(s)
Sex: Male
Height:
weight:
Med History: Was taking low dose of statins.
Allergies:

Serious Death: Yes
Date of Death: 2022[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Died
Reaction Start Date: 2022[redacted]
Reaction End Date: 202[redacted]
Reaction Description: The patient developed symptoms similar to pneumonia hours after receiving his covid vaccine booster (dose #3). Consulted a few days later and was diagnosed with mesothelioma. Was initially given 1 to 2 years to live, but died of the fast-growing cancer in only 2 months.

Suspect Product 1
DIN #/NPN #: unknown
Product Name: Covid-19 vaccine
Strength:
Strength other:
Dosage form:
Manufacturer: Moderna or Pfizer
Lot #:
Expiry date:
Product start date: 2022[redacted]
Product end date:
Dose: Booster dose (3rd injection)
Frequency:
Route of administration: Intramuscular
Route of administration - Other:
Indication: covid-19
Reported to Mfr: No
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Not applicable
Dechallenge: No
Rechallenge: Unknown

Concomitants:
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cancer	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Was taking low dose of statins.

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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ATIA - 19(1)

Canada Vigilance AER#:	001024414 (0)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Health Canada Santé Canada [redacted]

Canada Vigilance Adverse Reaction Reporting Form

Report of suspected adverse reactions to marketed health products in Canada

See instructions and information on adverse reaction reporting and confidentiality on Page 2.

Complete all mandatory items, marked by a *, and provide as much information as possible for the remaining items. PROTECTED WHEN COMPLETED – B**

A. Patient Information

1. Identifier [redacted]

2. Age	3. Sex*	4. Height	5. Weight
37 ☒ Years ☐ Months	☒ Male ☐ Female	_____ cm _____ feet	_____ kg _____ lbs

B. Adverse Reaction

1. Outcome attributed to adverse reaction (Select all that apply)

- ☒ Death: (yyyy-mm-dd)
- ☐ Life-threatening
- ☐ Hospitalization
- ☐ Hospitalization – prolonged
- ☐ Disability
- ☐ Congenital malformation
- ☐ Required intervention to prevent damage/impairment
- ☐ Other:

2. Reaction date (yyyy-mm-dd): 2022[redacted]

3. Report date (yyyy-mm-dd): 2022-[redacted]

4. Describe reaction or problem*

May 31, 2021 - Pfizer COVID-19 Vaccine
July 17, 2021 - Pzizer Vaccine

Family stated he was ill right after the third Moderna vaccine on [redacted] He phoned the physician and received betahistine and Zofran on [redacted] He had a witnessed cardiac arrest [redacted] He was resuscitated in hospital but transferred to another hospital for coronary angiogram. His report was cardiac results were pristine. He was found to have an intracerebral hemorrage. He was declared brain dead [redacted]. Underwent organ donation [redacted] Post mortem examination ordered and found no anatomical cause of death. Family informed his manner of death is Undetermined. Family believes this was vaccine related.

5. Relevant tests/laboratory data (including dates (yyyy-mm-dd))

Original blood samples were lost and could not be tested. However, hard copy results found from first day in hospital did not show thrombocytopenia. This did occur later in the admission. There were no thromoses compativle with a vaccine reaction.

6. Relevant history and pre-existing medical conditions (e.g. allergies, pregnancy, smoking/alcohol use, hepatic/renal dysfunction)

Nil

C. Suspected Health Product(s)

1. Name*, strength and manufacturer (if known)

#1 Modema COVID-19 mRNA SPIKEVAX

#2

2. Dose, frequency and route used

#1 0.2 mg/ml, 0.25 ml | #2

3. Therapy dates (or duration)

#1 From (yyyy-mm-dd) - To (yyyy-mm-dd): 2022-[redacted] | #2 From (yyyy-mm-dd) - To (yyyy-mm-dd)

4. Indication for use

#1 COVID-19 vaccine | #2

5. Reaction abated after use stopped or dose reduced

#1 ☐ Yes ☐ No ☒ Does not apply | #2 ☐ Yes ☐ No ☐ Does not apply

6. Lot #

#1 02510014
#2

7. Expiration

#1 (yyyy-mm-dd)
#2 (yyyy-mm-dd)

8. Reaction reappeared after reintroduction

#1 ☐ Yes ☒ No ☐ Does not apply | #2 ☐ Yes ☐ No ☐ Does not apply

9. Concomitant health products, excluding treatment of reaction (name, dose, frequency, route used and therapy dates (yyyy-mm-dd))

Betahistine and Zofran (information unavailable)

10. Treatment of reaction, including dates (yyyy-mm-dd)

See #4: 2022-[redacted] to 2022[redacted]

D. Reporter Information

1. Name*, occupation, address, telephone number*

[redacted]

2. Health professional? ☒ Yes ☐ No

3. Reported to manufacturer? ☐ Yes ☒ No

** As per the Treasury Board of Canada Secretariat Government Security Policy.

A program of **MedEffect™ Canada**

HC Pub.: 100251 (January 2011)

Canada

Page 1 of 3 Page 2 of 4
A2023000085

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ATIA - 19(1)

Plouffe, Sandra-Ann (HC/SC)

From: Prime Minister | Premier Ministre <PM@pm.gc.ca>
Sent: 2023-01-04 3:25 PM
To: [redacted]
Cc: hcminister.ministresc
Subject: Office of the Prime Minister / Cabinet du Premier ministre

Dear Mr[redacted]

I would like to acknowledge receipt of your most recent email sent to Prime Minister Justin Trudeau.

At the outset, I would like to express my heartfelt sympathies for the loss of your mother. My thoughts go out to you. Please be assured that your comments have been carefully reviewed.

I have taken the liberty of forwarding your email to the Honourable Jean-Yves Duclos, Minister of Health, so that he may also be made aware of your most recent correspondence.

Once again, thank you for writing.

[redacted]
Executive Correspondence Officer/Agente de correspondance Executive Correspondence Services/
Services de la correspondance de la haute direction

>>> From [redacted] Received : 22 Dec 2022 11:48:33 AM >>>

>>> Subject : Re: Office of the Prime Minister / Cabinet du Premier ministre >>>>

Was told that vaccine support programs are in place to help those that were affected. Would that not include my mother since she got the vaccine her blood pressure dropped until they induced coma then she Died.

On Tue, Apr 26, 2022, 10:38 AM Prime Minister | Premier Ministre, <PM@pm.gc.ca<mailto:PM@pm.gc.ca>> wrote:
Dear Mr. [redacted]

On behalf of Prime Minister Justin Trudeau, I would like to acknowledge receipt of your further email.

I would like to offer my heartfelt sympathy for the loss of your mother. Please allow me to also express my sincere regret for your father's health issues. You may be assured that your comments have been carefully reviewed.

I note that your previous email was forwarded to the former Minister of Health, the Honourable Patricia A. Hajdu. I have taken the liberty of sharing your further email with her successor, the Honourable Jean-Yves Duclos, Minister of Health, so that he may be made aware of your correspondence.

Once again, thank you for writing.

[redacted]
Executive Correspondence Officer/Agente de correspondance Executive Correspondence Services/
Services de la correspondance de la haute direction

ATIA - 19(1)

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>>> From [redacted] Received : 20 Apr 2022 11:30:20 PM >>>

>>> Subject : Re: Office of the Prime Minister / Cabinet du Premier ministre >>>>

According to the studies published on phizer vaccine myocarditis is a symptom .my mother was sent to hospital with symptoms the same as myocarditis. They induced coma and let her die .my father is left trying to survive with stage 4 lung and adrenal cancer and would like a more in depth assessment pls .

On Sun, Aug 15, 2021, 12:06 PM Prime Minister | Premier Ministre, <PM@pm.gc.ca<mailto:PM@pm.gc.ca><mailto:PM@pm.gc.ca>>> wrote:<mailto:PM@pm.gc.ca<mailto:PM@pm.gc.ca>

Dear Mr. [redacted]

I would like to acknowledge receipt of your email sent to Prime Minister Justin Trudeau.

At the outset, please allow me to express my heartfelt sympathies for the loss of your mother. You may be assured that your comments have been carefully reviewed.

I have taken the liberty of forwarding your email to the Honourable Patricia A. Hajdu, Minister of Health, so that she may be made aware of your correspondence.

Thank you for taking the time to write.

[redacted]
Executive Correspondence Officer/Agente de correspondance Executive Correspondence Services/
Services de la correspondance de la haute direction

>>> From : [redacted]
Received : 10 Aug 2021 09:35:51 PM >> [redacted]

>>> Subject : PM Web Site Comments - Seniors >>>>

Subject/Sujet : Seniors
Date : 2021/08/11 1:35:44 AM
First Name/Prénom : [redacted]
Last Name/Nom [redacted]
E-Mail/Adresse électronique :
[redacted]

Address/Adresse [redacted]
City/Ville [redacted]
Province : [redacted]
Postal Code/Code postal [redacted]
Telephone/Téléphone [redacted]

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Comments/Commentaires : My mom was pressured to take vaccines had 1st shot came home and blood pressure dropped bad she went to hospital they induced coma and she died.

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ATIA - 19(1)

Health Canada / Santé Canada

Canada Vigilance National Office
Health Products Surveillance and Epidemiology Bureau
Health Products and Food Branch
Tunney's Pasture AL: 1908C
Ottawa, (Ontario) K1A 0K9
Tel (toll-free): 1-866-234-2345
Fax (toll-free): 1-866-678-6789
canadavigilance@hc-sc.gc.ca

2023-01-25

[redacted]

Re: Adverse Reaction Number 001033681

Dear [redacted]

Thank you for submitting an adverse reaction report to the Canada Vigilance Program on 2023-01-25, regarding the following health product(s):

COVID-19 VACCINE

The information that you included in your report has been recorded in the Canada Vigilance Program database and assigned the Adverse Reaction Number 001033681. Please reference this number should you wish to report additional information on this event. Please note that Health Canada will contact you about your report only if additional information is required for its surveillance activities.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products that have been submitted by manufacturers and by hospitals, or by health professionals and consumers either directly to Health Canada or via the manufacturers and/or hospitals.

The information from adverse reaction reports as well as information from other sources of data is used to determine whether the benefits of a given health product continue to outweigh its risks and to take appropriate action to minimize any new risks. Such actions may include the update of the label of a health product in its authorized Canadian monograph, risk communication(s) to inform Canadians about possible new adverse reactions and/or a recall of the product.

For information on health products authorized for sale in Canada, you may wish to consult the following:

- Drug Product Database:
https://health-products.canada.ca/dpd-bdpp/index-eng.jsp

- Licensed Natural Health Products Database:
https://health-products.canada.ca/lnhpd-bdpsnh/index-eng.jsp

- Canada Vigilance Adverse Reaction Online Database:
https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html

- Health Canada's advisories, recalls and other communication on health products:
https://www.canada.ca/en/health-canada/services/drugs-health-products/advisories-warnings-recalls.html

We would like to thank you once again for your report, as your contribution and commitment to health product safety monitoring are appreciated.

Sincerely,

Canada Vigilance Program
Marketed Health Products Directorate
Health Canada

Canada

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ATIA - 19(1)

Health Canada / Santé Canada

Bureau national de Canada Vigilance
Bureau de la surveillance des produits de santé et de l'épidémiologie
Direction des produits de santé commercialisés
Pré Tunney, I.A. : 1908C
Ottawa (Ontario) K1A 0K9
Tél. (sans frais) : 1-866-234-2345
Téléc. (sans frais) : 1-866-678-6789
canadavigilance@hc-sc.gc.ca

2023-01-25

[redacted]

Objet : Déclaration d'effet indésirable 001033681

Cher / Chère [redacted]

Nous vous remercions d'avoir communiqué des renseignements sur des effets indésirables à Santé Canada, le 2023-01-25, concernant le(s) produit(s) de santé suivant(s) :

COVID-19 VACCINE

L'information que vous avez fournie dans votre déclaration a été enregistrée dans la base de données du Programme Canada Vigilance sous le numéro d'effet indésirable 001033681. Veuillez indiquer ce numéro si vous voulez fournir des renseignements supplémentaires au sujet de cet incident. Veuillez noter que Santé Canada ne vous contactera à propos de votre rapport que si des informations complémentaires sont requises pour ses activités de surveillance.

Le Programme Canada Vigilance est le programme de surveillance après la mise en marché de Santé Canada qui recueille et évalue les déclarations d'effets indésirables présumés associés aux produits de santé qui ont été soumises directement à Santé Canada par les professionnels de la santé et les consommateurs ou par l'entremise des détenteurs d'une autorisation de mise en marché ou des hôpitaux.

Les renseignements tirés des déclarations d'effets indésirables et d'autres sources de données servent à déterminer si les avantages d'un produit de santé donné continuent de l'emporter sur ses risques et à prendre les mesures appropriées pour minimiser les nouveaux risques. Ces mesures peuvent comprendre la mise à jour de l'étiquette d'un produit de santé dans sa monographie canadienne autorisée, la communication des risques pour informer les Canadiens au sujet des nouveaux effets indésirables possibles et/ou le retrait du produit.

Pour obtenir des renseignements sur les produits de santé dont la vente est autorisée au Canada, vous pouvez consulter les pages Web suivantes :

- Base de données sur les produits pharmaceutiques :
https://produits-sante.canada.ca/dpd-bdpp/index-fra.jsp

- Base de données sur les produits de santé naturels homologues :
https://produits-sante.canada.ca/lnhpd-bdpsnh/index-fra.jsp

- Base de données en ligne des effets indésirables de Canada Vigilance :
https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medeffet-canada/base-donnees-effets-indesirables.html

- Avis, mises en garde et retraits – Médicaments et produits de santé :
https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/avis-mise-garde-retrait.html

Nous vous remercions à nouveau pour votre déclaration. Votre contribution et votre participation à la surveillance de l'innocuité des produits de santé sont appréciées.

Cordialement,

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CIOMS FORM

ATIA - 19(1)

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
[redacted]	CANADA	[redacted]		1935	85 Years	Male	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Patient passed away [Death]
Fell down / fell down again [Fall]
Feeling unwell after Covid-19 vaccine [Feeling unwell]
Dizzy [Dizzy]

Case Description: This solicited case from Canada includes the initial report and one follow up report that were received by Sanofi (MFR No.: 2021SA080066) via a Patient Support Program (PSP_LEUPROLIDE [redacted] on [redacted] 2021 and on [redacted] 2021, from the patient's wife, who reported that the patient just got the COVID vaccine and he was

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 30 mg {Lot # 11188A; 11187A; UNK}
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 30 mg, q 4 month
#2)

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous
#2) Unknown

17. INDICATION(S) FOR USE
#1) Prostate cancer (Prostate cancer)
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) 14-NOV-2020 / Unknown
#2) Unknown

19. THERAPY DURATION
#1) Unknown
#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Prostate cancer (Prostate cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Tolmar, Inc.
[redacted] PharmD
701 Centre Ave
Fort Collins, CO 80526 UNITED STATES

26. REMARKS

24b. MFR CONTROL NO.
21CA025930

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
[redacted]-2021

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Study

DATE OF THIS REPORT
[redacted] 2021

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

[redacted] 2021 15:58

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ATIA - 19(1)

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

feeling unwell (Feeling unwell), was dizzy (Dizzy) and fell down and fell down again (Fall), during Eligard (leuprolide acetate) 30 mg treatment for prostate cancer. COVID vaccine for COVID prophylaxis was considered a co-suspect medication. This case concerned an 85 year-old male patient. The reports were sent to Tolmar on [redacted] 2021 and on [redacted] 2021, respectively. The needle component of the constituent device was not identified in the report.

The patient's medical history was not reported. Current condition included prostate cancer.

Concomitant medications were not provided.

On 07 Nov 2016, the patient began receiving Eligard 30 mg, every four months, subcutaneously, for the treatment of prostate cancer (Lot number and Expiration date not reported). On 14 Nov 2020, the patient received his latest Eligard 30 mg dose, every four months, subcutaneously (Lot number carton: not reported; Expiration date: not reported; Lot number Syringe A: 11188A; Expiration date: Dec 2021; Lot number Syringe B: 11187A; Expiration date: Jan 2022) for the treatment of prostate cancer. On an unknown date, the patient received the COVID vaccine (dose, frequency, route of administration not reported) for COVID prophylaxis.

The patient's wife reported that on an unspecified date, time to onset unknown after Eligard treatment, but described as after he "just got the COVID vaccine," the patient felt unwell, was dizzy and fell down. The patient's wife reported that the patient was still experiencing side effects from the COVID vaccine (it was not specified if they were the same side effects initially reported) and the patient fell down again. The patient's wife asked to postpone the patient's injection from [redacted] 2021 to [redacted] 2021 so the patient could rest. No further details were provided.

Action taken for COVID vaccine in response to the events was unknown and for Eligard treatment was dose not changed (ongoing); de-challenge and re-challenge were not applicable. The outcome of the events was not recovered/not resolved.

No laboratory data information was provided.

The reporter did not assess seriousness of the events and assessed causality of the events with respect to Eligard therapy as not related.

On [redacted] 2021, follow-up information was received by Sanofi (Mfr no.: 2021SA080066) from a consumer (Patient's Wife) and was sent to Tolmar on [redacted] 2021. Added new serious event of "Patient passed away (Death)". Updated action taken, dechallenge and rechallenge and upon recipt of follow-up information. This case was upgraded to serious.

Per the reporting patient's wife, the nurse performed a follow up call to see if the patient was feeling better and if ready for his next injection and the wife reported the patient passed away the other day (Date not specified). The cause of death was unknown. The patient was 85 years-old at the time of the event and it was unknown whether if an autopsy was performed. The action taken with the suspect product, dechallenge and rechallenge were not applicable. The outcome of the event was fatal.

The reporter assessed the event as serious (Death) and did not assess the causality of the event regarding Eligard therapy.

Evaluator Comment (Tolmar): This elderly male patient passed away during Eligard therapy for prostate cancer (serious due to a fatal outcome (death)). Before his death, he fell (Fall) and experienced Feeling unwell and was Dizzy. COVID-19 vaccine is a co-suspect. Fall, Feeling unwell, and Dizzy are assessed as non-serious. The causal role of Eligard in the patient's death is considered not assessable due to lack of information regarding the cause of death, autopsy results, the clinical state of underlying prostate cancer, circumstances preceding patient's death, other relevant medical history, all concomitant medications received and supportive investigations and diagnosis relevant to cause of death. However, the underlying prostate cancer and the patient's age are pre-existing risk factors. The causal role of Eligard for Fall, Feeling unwell, and Dizzy is assessed as not related to Eligard therapy. As reported, co-suspect COVID-19 VACCINE can likely explain the Dizziness and Feeling unwell, which led to his Falls. The events are assessed as not related to the device component of Eligard.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 30 mg; Regimen #2	30 mg, q 4 month; Subcutaneous	Prostate cancer (Prostate cancer)	07-NOV-2016 / Unknown; Unknown
#2) Eligard® Unspecified Device (Leuprolide	; Unknown	Unknown	Unknown;

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Mfr. Control Number: 21CA025930

ATIA - 19(1)

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
acetate) Subcutaneous injection {Lot # 11188A; 11187A; UNK}; Regimen #1			Unknown
#3) COVID-19 VACCINE (COVID-19 VACCINE) ; Regimen #1	Unknown; Unknown	COVID prophylaxis (COVID-19 prophylaxis)	Unknown; Unknown

[redacted]2021 15:58

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-03-23 10:09 AM
To: [redacted]@sanofi.com
Cc: canada.pharmacovigilance@sanofi.com; Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: RE: Health Canada Follow-Up Clarification Request

EXTERNAL

Good morning,

Re: Health Canada Follow-Up Clarification Request

As a result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified individual case safety reports (ICSRs) where clarification is needed. Please investigate, clarify and resubmit case information for the following ICSRs that require clarification or have discrepancies which may impact case evaluation and/or signal detection:

MAH Case Number	Canada Vigilance Case Number	Clarification Requested
Safety report ID: 21CA025930 reported to HC on behalf of Tolmar, Inc Fort Collins, CO, USA concerning suspect drugs: **ELIGARD** (Sanofi-Aventis Canada Inc.) and co-suspect: "**COVID-19 vaccine**" (unspecified MAH) and stating the following in the case narrative: Initial report and one follow up report that were received by **Sanofi (MFR No.: 2021SA080066) via a Patient Support Program** (PSP_LEUPROLIDE[redacted]) Received by Health Canada on: 19/03/2021	000943098	Specifically, our evaluators wish to request the following information: • Please provide any information regarding the specific COVID-19 vaccine administered, including type of vaccine, date of administration, lot #, first or second dose, etc. • Please provide any information pertaining to any medical diagnosis pertaining to the cause of death and any autopsy details, if available. • Please provide any information pertaining to the patient's general clinical state at the time of vaccination. Specifically, please provide any details regarding the status of the patient (e.g. bedridden, up with assistance, independent etc.), and laboratory testing (eg. Renal function, hematology, liver function). • Please provide any information pertaining to other medications, particularly sedatives and analgesics. • Please provide any symptoms associated with the vaccination (e.g. fever etc.).

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		• Please provide any information regarding any evaluation or treatment after the fall.

Please provide a response within 15 days upon receipt of this correspondence, March 23rd, 2021, in order to allow for sufficient time for case evaluation. Kindly send response to our generic Canada Vigilance COVID-19 Vaccine account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca) with a cc to myself, Michelle Séguin: michelle.seguin@canada.ca.

If you require further information within the scope of this request, please do not hesitate to contact me.

Thank you in advance for your much appreciated collaboration.

Sincerely,

Michelle Séguin on behalf of:
The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

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ATIA - 19(1)

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Dawson, Dianne (HC/SC)

From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-04-07 2:33 PM
To: Seguin, Michelle (HC/SC)
Subject: 000943098 Health Canada Follow-Up Clarification Request Sanofi

From [redacted]@sanofi.com>
Sent: 2021-04-07 10:41 AM
To: Seguin, Michelle (HC/SC) <michelle.seguin@canada.ca>; Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca>
Cc: Canada Pharmacovigilance /CA <canada.pharmacovigilance@sanofi.com>; [redacted]@sanofi.com>
Subject: RE: Health Canada Follow-Up Clarification Request_Sanofi 2021SA080066 (Tolmar 21CA025930)

Dear Ms. Séguin,

In an effort to gather additional information and answers to your questions below, Sanofi has actively attempted to reach the Healthcare professional involved in the care of this patient.
To date, no additional information has been received by Sanofi relative to this report. Shall further information become available, Sanofi will ensure that this is submitted to HC via the standard expediting reporting procedure.

Thank you,
Kind regards,

[redacted]
Country Safety Head (CSH) Back-up / Project Leader, Pharmacovigilance
(T [redacted] (F) [redacted] (M [redacted]
SANOFI CANADA – 2905, Pl. Louis-R.-Renaud – Laval (QC) – Canada – H7V 0A3
SANOFI
www.sanofi.ca

From: [redacted]/CA
Sent: Tuesday, March 23, 2021 10:40 AM
To: michelle.seguin@canada.ca; Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca>
Cc: Canada Pharmacovigilance /CA <canada.pharmacovigilance@sanofi.com>; [redacted]@sanofi-aventis.com) [redacted]@sanofi.com>
Subject: RE: Health Canada Follow-Up Clarification Request_Sanofi 2021SA080066 (Tolmar 21CA025930)

Dear Ms. Séguin,

Thank you for your message, it has been well received.
We will review the information requested and respond as required.

Thank you,
Kind regards,

ATIA - 19(1)

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[redacted]
Country Safety Head (CSH) Back-up / Project Leader, Pharmacovigilance
(T) [redacted] (F [redacted] (M) [redacted] [redacted]@sanofi.com
SANOFI CANADA – 2905, Pl. Louis-R.-Renaud – Laval (QC) – Canada – H7V 0A3
SANOFI
www.sanofi.ca

From: Seguin, Michelle (HC/SC) <michelle.seguin@canada.ca> **On Behalf Of** Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: Tuesday, March 23, 2021 10:09 AM
To [redacted]@sanofi.com>
Cc: Canada Pharmacovigilance /CA <canada.pharmacovigilance@sanofi.com>; Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca>
Subject: RE: Health Canada Follow-Up Clarification Request

EXTERNAL

Good morning,

Re: Health Canada Follow-Up Clarification Request

As a result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified individual case safety reports (ICSRs) where clarification is needed. Please investigate, clarify and resubmit case information for the following ICSRs that require clarification or have discrepancies which may impact case evaluation and/or signal detection:

MAH Case Number	Canada Vigilance Case Number	Clarification Requested
Safety report ID: 21CA025930 reported to HC on behalf of Tolmar, Inc Fort Collins, CO, USA concerning suspect drugs: **ELIGARD** (Sanofi-Aventis Canada Inc.) and co-suspect: **"COVID-19 vaccine"** (unspecified MAH) and stating the following in the case narrative: Initial report and one follow up report that were received by **Sanofi (MFR No.: 2021SA080066) via a Patient Support Program** (PSP_LEUPROLIDE[redacted] Received by Health Canada on: 19/03/2021	000943098	Specifically, our evaluators wish to request the following information: • Please provide any information regarding the specific COVID-19 vaccine administered, including type of vaccine, date of administration, lot #, first or second dose, etc. • Please provide any information pertaining to any medical diagnosis pertaining to the cause of death and any autopsy details, if available. • Please provide any information pertaining to the patient's general clinical state at the time of vaccination. Specifically, please provide any details regarding the status of the patient (e.g. bedridden, up with assistance, independent etc.), and laboratory testing (eg. Renal function, hematology, liver function).

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		• Please provide any information pertaining to other medications, particularly sedatives and analgesics. • Please provide any symptoms associated with the vaccination (e.g. fever etc.). • Please provide any information regarding any evaluation or treatment after the fall.

Please provide a response within 15 days upon receipt of this correspondence, March 23rd, 2021, in order to allow for sufficient time for case evaluation. Kindly send response to our generic Canada Vigilance COVID-19 Vaccine account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca) with a cc to myself, Michelle Séguin: michelle.seguin@canada.ca.

If you require further information within the scope of this request, please do not hesitate to contact me.

Thank you in advance for your much appreciated collaboration.

Sincerely,

Michelle Séguin on behalf of:
The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

"

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ATIA - 19(1)

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
[redacted]	CANADA	[redacted]		1935	85 Years	Male	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Passed away due to natural prostate cancer progression [Progression of prostate cancer]
Fell down / fell down again [Fall]
Feeling unwell after Covid-19 vaccine [Feeling unwell]
Dizzy [Dizzy]

Case Description: This solicited case from Canada includes the initial report and one follow up report that were received by Sanofi (MFR No.: 2021SA080066) via a Patient Support Program (PSP_LEUPROLIDE[redacted] on [redacted] 2021 and on [redacted] 2021, from the patient's

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED Date: 11-MAR-2021
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- [ ] INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [ ] OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 30 mg {Lot # 11188A; 11187A; UNK}
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous (Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 30 mg, q 4 month	#1) Subcutaneous
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Prostate cancer (Prostate cancer)
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 14-NOV-2020 / Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Prostate cancer (Prostate cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Tolmar, Inc.
[redacted] PharmD
701 Centre Ave
Fort Collins, CO 80526 UNITED STATES

26. REMARKS

24b. MFR CONTROL NO.
21CA025930

24c. DATE RECEIVED BY MANUFACTURER
26-MAY-2021

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☒ OTHER: Study

DATE OF THIS REPORT
01-JUN-2021

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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ATIA - 19(1)

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

wife, who reported that the patient just got the COVID vaccine and he was feeling unwell (Feeling unwell), was dizzy (Dizzy) and fell down and fell down again (Fall), during Eligard (leuprolide acetate) 30 mg treatment for prostate cancer. COVID vaccine for COVID prophylaxis was considered a co-suspect medication. This case concerned an 85 year-old male patient. The reports were sent to Tolmar on [redacted] 2021 and on [redacted] 2021, respectively. The needle component of the constituent device was not identified in the report.

The patient's medical history was not reported. Current condition included prostate cancer.

Concomitant medications were not provided.

On 07 Nov 2016, the patient began receiving Eligard 30 mg, every four months, subcutaneously, for the treatment of prostate cancer (Lot number and Expiration date not reported). On 14 Nov 2020, the patient received his latest Eligard 30 mg dose, every four months, subcutaneously (Lot number carton: not reported; Expiration date: not reported; Lot number Syringe A: 11188A; Expiration date: Dec 2021; Lot number Syringe B: 11187A; Expiration date: Jan 2022) for the treatment of prostate cancer. On an unknown date, the patient received the COVID vaccine (dose, frequency, route of administration not reported) for COVID prophylaxis.

The patient's wife reported that on an unspecified date, time to onset unknown after Eligard treatment, but described as after he "just got the COVID vaccine," the patient felt unwell, was dizzy and fell down. The patient's wife reported that the patient was still experiencing side effects from the COVID vaccine (it was not specified if they were the same side effects initially reported) and the patient fell down again. The patient's wife asked to postpone the patient's injection from [redacted] 2021 to [redacted] 2021 so the patient could rest. No further details were provided.

Action taken for COVID vaccine in response to the events was unknown and for Eligard treatment was dose not changed (ongoing); de-challenge and re-challenge were not applicable. The outcome of the events was not recovered/not resolved.

No laboratory data information was provided.

The reporter did not assess seriousness of the events and assessed causality of the events with respect to Eligard therapy as not related.

On [redacted] 2021, follow-up information was received by Sanofi (Mfr no.: 2021SA080066) from a consumer (Patient's Wife) and was sent to Tolmar on [redacted] 2021. Added new serious event of "Patient passed away (Death)". Updated action taken, dechallenge and rechallenge and upon receipt of follow-up information. This case was upgraded to serious.

Per the reporting patient's wife, the nurse performed a follow up call to see if the patient was feeling better and if ready for his next injection and the wife reported the patient passed away the other day (Date not specified). The cause of death was unknown. The patient was 85 years-old at the time of the event and it was unknown whether if an autopsy was performed. The action taken with the suspect product, dechallenge and rechallenge were not applicable. The outcome of the event was fatal.

The reporter assessed the event as serious (Death) and did not assess the causality of the event regarding Eligard therapy.

On 26 May 2021, follow up information was received by Sanofi (Mfr. No.: 2021SA080066) from a healthcare professional and was sent to Tolmar on 28 May 2021. Added healthcare professional as new reporter and causality assessment from this new reporter. Added date and cause of death. Updated event description from passed away (Death) to passed away due to natural prostate cancer progression (Progression of prostate cancer). Upon follow-up information was received the case met different reportability criteria. It was submitted as expedited report previously, but it does now meet criteria for periodic reporting.

On [redacted] 2021, patient passed away due to natural prostate cancer progression.

The healthcare professional assessed the event passed away due to natural prostate cancer progression as serious (Death) and did not consider the patient´s death was caused by Eligard therapy. Seriousness and causality assessment for the previously reported events was not provided.

No additional details were provided.

Evaluator Comment (Tolmar): This elderly male patient passed away due to natural prostate cancer progression during Eligard therapy for prostate cancer (serious due to a fatal outcome (death)). Before his death, he fell (Fall) and experienced Feeling unwell and was Dizzy. COVID-19 vaccine is a co-suspect. Fall, Feeling unwell, and Dizzy are assessed as non-serious. The causal role of Eligard in the natural prostate cancer progression is assessed as not related as the event can be explained by the inherent nature of malignancy to progress with time. The causal role of Eligard for Fall, Feeling unwell, and Dizzy is assessed as not related to Eligard therapy. As reported, co-suspect COVID-19 VACCINE can likely explain the Dizziness and Feeling unwell, which led to his Falls. The events are assessed as not related to the device component of Eligard.

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ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Eligard® (Leuprolide acetate) Subcutaneous injection, 30 mg; Regimen #2	30 mg, q 4 month; Subcutaneous	Prostate cancer (Prostate cancer)	07-NOV-2016 / Unknown; Unknown
#2) Eligard® Unspecified Device (Leuprolide acetate) Subcutaneous injection {Lot # 11188A; 11187A; UNK}; Regimen #1	; Unknown	Unknown	Unknown; Unknown
#3) COVID-19 VACCINE (COVID-19 VACCINE) ; Regimen #1	Unknown; Unknown	COVID prophylaxis (COVID-19 prophylaxis)	Unknown; Unknown

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Canada Vigilance AER#:	E2B_03730867 (3)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210305 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021018220(4)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210109 CCYYMMDD	20210302 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021018220

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021018220

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			90 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03730867 (3)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	COVID-19
26.0	Drug ineffective

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
SINGLE DOSE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2020[redacted] CCYYMMDD	2020[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** COVID-19	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Drug ineffective	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Drug ineffective	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED OF COVID-19/DEVELOPING SYMPTOMS 18 DAYS AFTER HIS INOCULATION

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Drug ineffective		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Drug ineffective		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED OF COVID-19/DEVELOPING SYMPTOMS 18 DAYS AFTER HIS INOCULATION

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) COVID-19		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) COVID-19		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Fatal	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03730867 (3)	Page#4

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable consumer. A 90-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on [redacted]2020 at age of 90 years old at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient died of COVID-19 on Wednesday [redacted]2021) at the Hospital. The patient was given the vaccine on [redacted]2020 and was due to be vaccinated 21 days later. His second dose was delayed because of provincial plan to vaccinate as many people as quickly as possible. The patient started developing symptoms 18 days after his inoculation so the second dose would not have helped him. No other details provided.

Information on lot/batch number has been requested.

Follow-up (26Jan2021): New information received from a contactable consumer includes: reporter information.

Follow up(28Jan2021): No follow up attempts are needed, No further information is expected.

Follow-up (02Mar2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	COVID-19	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug ineffective	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03883198 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210318 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021252679(3)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 2021[redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-2021252679

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-2021252679

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 83 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03883198 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
SINGLE DOSE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
6 Days	132 Hours	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	LASIX [FUROSEMIDE]	
Active Substance names (B.4.k.2.2)		
FUROSEMIDE		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) BISOPROLOL	
Active Substance names (B.4.k.2.2) bisoprolol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) NITROGLYCERIN	
Active Substance names (B.4.k.2.2) nitroglycerin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CLOPIDOGREL BISULFATE	
Active Substance names (B.4.k.2.2)		
clopidogrel bisulfate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAD PASSED A WAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
6 Days	132 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FELL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fall		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fall		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer. An 83-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown), via an unspecified route of administration in the right arm on [redacted]2021 12:00 at a single dose for COVID-19 immunisation. Medical history included congestive heart failure, cancer (Colon, liver & possibly bowel), diabetes, dementia, fall on [redacted]021, fractured her skull on [redacted]021, and palliative therapy from Nov2020. Concomitant medication included furosemide (LASIX); bisoprolol; glyceryl trinitrate (NITRODERM), and clopidogrel bisulfate (PLAVIX). The patient fell at home in her bedroom. She was conscious when speaking with her daughter, but then was unresponsive when a family member came to help her up off the floor and had passed away on [redacted]2021. As of [redacted]2021, the doctor said that she was unaware that the patient had passed away. She said that it is unlikely to be linked to the vaccine as this patient had a lot of diseases and was taken a lot of medication. She cannot provide more information as she was unaware of what happened. As of [redacted]2021, the reporter could not provide any information pertaining to the cause of death as indicated on the death certificate. The reporter could not provide any information regarding any concomitant medications. Specifically, any analgesics or sedatives. The reporter could also not provide any information regarding any recent laboratory results, any information regarding clinical status prior to terminal event. She reported that the reasons for her prior falls would have been weakness and fatigue from her heart condition. The patient was not diagnosed with COVID-19 before the vaccination. The patient was not tested positive to COVID-19 after the vaccination. The outcome of event fell was unknown. The patient passed away on [redacted]021. An autopsy was not performed.

Information about Lot/Batch number has been requested.

Follow-up [redacted]2021): New information reported from a contactable physician via safety phone line included: new reporter, new causality assessment provided, clinical course details.This follow-up report is also being submitted to amend previously reported information: event "fell" added.

Information about Lot/Batch number has been requested.

Follow-up [redacted]021): New information was received from the same contactable consumer includes: clinical course details.

No follow-up attempts required. No further information expected
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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The company cannot completely exclude a reasonable possibility that the administration of vaccine BNT162B2 could have contributed to the patient's demise. The company processes "death cause unknown" cases as possibly related and documents them as related in the global safety database unless information is provided that allows the Company to exclude that there is a reasonable possibility of relatedness to the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congestive heart failure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cancer	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
Colon, liver & possibly bowel		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dementia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fall	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
202[redacted] CCYYMM		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Skull fracture	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
2021[redacted] CCYYMM		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Palliative care

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
202011 CCYYMM		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03986299 (3)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210521 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021361855(4)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	20210518 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021361855

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021361855

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			89 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_03986299 (3)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebrovascular accident

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03986299 (3)	Page#3

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNKNOWN DOSE, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 3330 Minutes	**Last period (B.4.k.13.2)** 3330 Minutes	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebrovascular accident	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebrovascular accident	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FINASTERIDE	
Active Substance names (B.4.k.2.2) finasteride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PANTOPRAZOLE	
Active Substance names (B.4.k.2.2)		
pantoprazole		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) APO-LEVOCARB	
Active Substance names (B.4.k.2.2) carbidopa levodopa		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TAMSULOSIN	
Active Substance names (B.4.k.2.2) tamsulosin hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) LOPERAMIDE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) loperamide hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Diarrhea
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Canada Vigilance AER#:	E2B_03986299 (3)	Page#9

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MIRTAZAPINE	
Active Substance names (B.4.k.2.2)		
mirtazapine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBROVASCULAR ACCIDENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebrovascular accident		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Cerebrovascular accident		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
3330 Minutes	3330 Minutes	Fatal

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03986299 (3)	Page#10

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable consumer (patient's daughter). An 89-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in the left arm on [redacted]2021 at 16:30 (Lot number: Not reported, Expiration date: Not reported) (at the age of 89-year-old) as a single dose for COVID-19 immunization. The patient medical history included Parkinson's disease (slow type for several years, difficult to control, difficulty walking, dressing, dizziness and was forgetting more frequently) from 1980 and ongoing, ongoing dyspepsia, ongoing depression (onset date, approximately 3 years ago), diarrhoea from an unknown date and unknown if ongoing, ongoing dizziness and was forgetting more frequently and her father's health condition was deteriorating. Patient had no allergies to medications, food, or other products. Patient had no serious heart condition or other conditions. His last blood test was perfect. Concomitant medications included finasteride taken for an unspecified indication; pantoprazole taken for an unspecified indication; carbidopa/levodopa (APO-LEVOCARB) taken for an unspecified indication; tamsulosin taken for an unspecified indication; loperamide hydrochloride (LOPERAMID) taken for diarrhoea; mirtazapine (MIRTAZAPIN) taken for an unspecified indication, for all concomitants start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient was not diagnosed with COVID-19 prior vaccination. The reporter stated that her father received the vaccine and felt well after administration. On [redacted]021, the patient had cerebrovascular accident. It was reported that the patient was found unconscious and his wife called the emergency line. The reporter stated that, when the ambulance arrived, the patient still had a pulse, and they mentioned that the reaction was probably neurological. When the patient arrived at the hospital, they called his wife to inform her that he was not feeling well and when patient's wife arrived at the hospital patient had already passed away. Cerebrovascular accident was not confirmed, but daughter and wife thought what the patient experienced. The reporter stated that her father's health condition was deteriorating for the past few years. The patient did not receive any treatment for the event. Since the vaccination, the patient has not been tested for COVID-19. The patient died on [redacted]2021. An autopsy was not performed.

Follow-up (09Apr2021): The following information has been reported by the same contactable consumer (patient's daughter) which included significant information regarding patient medical history and event information was added.

Follow-up (12Apr2021): New information reported from the same contactable consumer (patient's daughter) received via the Medical Information includes concomitant medications.

Follow-up (18May2021): This follow-up is being submitted to notify that the batch/lot number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood test	perfect	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Parkinson's disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
1980 CCYY	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspepsia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Depression	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		
onset date, approximately 3 years ago		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dizziness	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	General physical health deterioration	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diarrhoea	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebrovascular accident	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date (B.1.8e)**
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_03991991 (3)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210430 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021375885(4)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	202[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2) CA-PFIZER INC-2021375885

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021375885

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			85 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	ER1742	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
SINGLE DOSE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD	202[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
14935 Minutes	14935 Minutes	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Explosive diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Explosive diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nauseous	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nauseous	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Weakness generalized	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Weakness generalized	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) **Current reaction**

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heart attack
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Myocardial infarction

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
14935 Minutes	14935 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEOUS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Nauseous
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nausea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
535 Minutes	535 Minutes	Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

EXPLOSIVE DIARRHEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Explosive diarrhea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Diarrhoea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
535 Minutes	535 Minutes	Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GENERALIZED WEAKNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Weakness generalized
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Asthenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
535 Minutes	535 Minutes	Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VOMITING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vomiting
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vomiting

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
535 Minutes	535 Minutes	Unknown

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ATIA - 19(1)

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (patient's son), a contactable physician and Other Health Professional. An 85-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER1742), intramuscular in left deltoid, on [redacted]2021 at 15:05 PM, at a single dose, for COVID-19 immunization. The patient's medical history included severe ulcerative colitis and asthma since a long time; the patient used to practice yoga and weighcement bags every week for muscular fitness. There were no concomitant medications. Past drug history included budesonide/formoterol fumarate (SYMBICORT) for asthma. There were no other vaccinations within four weeks prior to the first administration date of the suspect vaccine. The patient's son was just calling to find out about the side effects with the COVID-19 vaccine. The patient got vaccinated and then 3 weeks later [redacted]2021), he was nauseous and had explosive diarrhea and generalized weakness. The patient had nausea and vomiting on [redacted]2021 for which the patient had ginger to chew as therapeutic measures. The patient died of a heart attack on [redacted]2021 (passed away). The patient was found dead in his residence on [redacted]2021. According to the patient's son, patient had his last health check-up 2 months ago [redacted]2021) and was in perfect condition, had no health issues, was practicing yoga and weighing cement bags every week for muscular fitness. The patient's son and his family are shocked and wanted answers. The doctor confirmed that the death is not associated with an anaphylactic shock. He confirmed that heart attack (heart stopped) is the cause of death. The doctor has not seen patient for the last 18 months. The patient was suffering from a severe ulcerative colitis and asthma since a long time and the doctor had prescribed budesonide/formoterol fumarate (SYMBICORT) to the patient in the past. He doesn't know if the death is related to the vaccine besides the fact that it is close in time. The physician said that the patient was seeing another doctor at the medical clinic. The outcome of heart attack was fatal. The outcome of the remaining events was unknown. The patient died on [redacted]2021. It was not reported if an autopsy was performed.
Conclusion: The complaint for "PFIZER-BIONTECH COVID-19 VACCINE" was investigated. The investigation included reviewing the involved batch records, deviation investigation and an analysis of the complaint history for the reported lot and product type. The final scope was determined to be the associated lot(s) of the reported lot ER1742. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation and stability. PGS Puurs concludes that the reported defect is not representative of the quality of the batch and the batch remains acceptable. The NTM process determined that no regulatory notification was required. The reported defect could not be confirmed. No root cause or CAPA were identified as the complaint was not confirmed
Follow-up [redacted]2021): New information reported from a contactable physician includes: additional reporter, physician's causality assessment (death not associated with an anaphylactic shock and unknown if death has causal relationship with the vaccine besides the temporal relationship), patient's race, additional medical history (ulcerative colitis and asthma) and past drug history.

Follow-up attempts are completed. No further information is expected.

Follow-up [redacted]021): New information received from a contactable healthcare professional (medical assistant) includes additional reporter.

Follow-up [redacted]2021): New information has been reported as conclusion following investigation by the Product Quality Group included: investigation results.

No follow-up attempts are needed. No further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The Company concurs with the HCP reporter that the fatal event heart attack represents an intercurrent medical condition and unrelated to BNT162B2.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
202[redacted] CCYYMM	Physical examination	In perfect condition

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Exercise adequate	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Ulcerative colitis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Asthma	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)
prescribed Symbicort

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)
SYMBICORT

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
26.0	Asthma
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Canada Vigilance AER#:	E2B_03991991 (3)	Page#7

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04034593 (3)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211126 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A305379()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210413 CCYYMMDD	20211121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A305379

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	P2B 04034593 [redacted] CA-AstraZeneca-2021A305379

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVISHIELD VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02512947 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml		
Dosage text (B.4.k.6)		
Dose Unknown0.5mL ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VACCINE-INDUCED PROTHROMBOTIC IMMUNE THROMBOCYTOPENIA (VIPIT)

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Immune thrombocytopenia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Immune thrombocytopenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			7 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombosis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL BLOOD CLOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Clot blood
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA WITH THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombosis with thrombocytopenia syndrome
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombosis with thrombocytopenia syndrome

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombocytopenia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombocytopenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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Unknown

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a female patient (age not provided) of Unknown ethnic origin.

The patient's past and current medical history included thromboembolectomy (dates not reported) and angioplasty (dates not reported). No concomitant products were reported.

The patient received Covishield Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadoxl ncov-19)) of dose unknown once/single administration, via intramuscular route, for product used for unknown indication on an unknown date. On an unknown date, the patient experienced vaccine-induced prothrombotic immune thrombocytopenia (vipit) (preferred term: Immune thrombocytopenia). On an unknown date, the patient experienced thrombosis (preferred term: Thrombosis). On an unknown date, the patient experienced cerebral blood clot (preferred term: Thrombosis). On an unknown date, the patient experienced thrombocytopenia with thrombosis (preferred term: Thrombosis with thrombocytopenia syndrome). On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia). On an unknown date platelet count was conducted and found to be less than 150x109 per L.

Action taken with Covishield Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was Not Applicable. The outcome of the event(s) of vaccine-induced prothrombotic immune thrombocytopenia (vipit), thrombosis, thrombocytopenia with thrombosis and thrombocytopenia was unknown. The patient died from the event of cerebral blood clot on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was cerebral blood clot.

The event such as cerebral blood clot was considered serious by the reporter due to death. The event such as vaccine-induced prothrombotic immune thrombocytopenia (vipit) was considered serious by the reporter due to hospitalisation. The events such as vaccine-induced prothrombotic immune thrombocytopenia (vipit), thrombosis, thrombocytopenia with thrombosis and thrombocytopeniawere considered serious by the reporter due to important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow up information received by AstraZeneca/MedImmune on 14-04-2021 from consumer via spontaneous source: New serious event of induced prothrombotic immune thrombocytopenia was added as new event, reporter consumer added, narrative amended.

Follow up of Insignificant information received by AstraZeneca/MedImmune on 20-04-2021 from consumer via spontaneous source: New seriousness criteria of hospitalised for the event of vaccine-induced prothrombotic immune thrombocytopenia (vipit.) added. Reporter other added, narrative amended.

Summary of follow-up information received by AstraZeneca on 21-NOV-2021. Regulatory authority with id was updated, Indication for suspect as product used for unknown indication was updated, frequency as once was updated and THROMBOCYTOPENIA WITH THROMBOSIS was updated. Corrected Report 26-NOV-2021: Lot number was removed,Age group updated to NI, lab as report platelet count was updated,and disease such as ANGIOPLASTY and THROMBOEMBOLECTOMY, Action taken was updated to Not Applicable and narrative updated.
CAUSE OF DEATH: CEREBRAL BLOOD CLOT Lab Test #1 : 10035525
COVISHIELD is a Verity Pharmaceuticals Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Thrombosis (Preferred Term: Thrombosis) in combination with thrombocytopenia (Preferred Term: Thrombosis with thrombocytopenia syndrome, Preferred Term: Thrombocytopenia and Preferred Term: Immune thrombocytopenia) is listed in the company core data sheet of AZD1222. However, since the event Thrombosis was reported with a fatal outcome, it is considered unlisted. Patient's past and current medical history of thromboembolectomy and angioplasty may suggest a prior coagulation disorder that could be considered as a confounding factor for the event of Thrombosis. The cause of death was cerebral blood clot. Due to limited information on patient´s age, personal and family medical history, baseline health condition prior to vaccination, circumstances leading to the event, vaccination date and onset dates of the events, risk factors (malignancy, recent surgery, arrhythmia, deep vein thrombosis and familial blood clotting disorders), etiological and diagnostic work up (physical and clinical evvaluation, blood chemistry panel and cell count, coagulation panel with D dimer, imaging studies, autopsy report if performed), physician report/hospital discharge summary, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Platelet count		
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

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Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thromboembolectomy	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Angioplasty	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Canada Vigilance AER#:	E2B_04034593 (3)	Page#6

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	PRIVACY	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04060632 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210507 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021418643(3)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20210504 CCYYMMDD	**Disabling/Incapacitating?**	Yes
		Life threatening?	Yes
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-2021418643

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-2021418643

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 73 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04060632 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Aspiration pneumonia
26.0	Ischemic stroke
26.0	Pyrexia
26.0	Seizure
26.0	Sepsis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EN1196	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
SINGLE DOSE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

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Drug Reaction relatedness (B.4.k.18)

MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Aspiration pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Aspiration pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Balance difficulty	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Balance difficulty	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebellar disorder NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebellar disorder NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gait disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Gait disturbance	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ischemic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ischemic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pyrexia	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pyrexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Seizure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Seizure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sepsis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sepsis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swallowing difficult	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swallowing difficult	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unconscious	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unconscious	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) NABILONE	
Active Substance names (B.4.k.2.2) nabilone		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) .5 Milligram 1 (Days)		
Dosage text (B.4.k.6) 0.5 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0 26.0	Indication (B.4.k.11b) Dementia Agitation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RISPERDAL	
Active Substance names (B.4.k.2.2)		
risperidone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2.5 Milligram 1 (Days)		
Dosage text (B.4.k.6)		
2.5 mg, daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Dementia Agitation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TRAZODONE	
Active Substance names (B.4.k.2.2) trazodone		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 175 Milligram 1 (Days)		
Dosage text (B.4.k.6) 175 mg, daily (75mg morning, 50mg afternoon, 50mg evening)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0 26.0	Indication (B.4.k.11b) Dementia Agitation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ENALAPRILAT	
Active Substance names (B.4.k.2.2) enalaprilat		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 10 Milligram 1 (Days)		
Dosage text (B.4.k.6) 10 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Blood pressure
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	HYDROCHLOROTHIAZIDE	
Active Substance names (B.4.k.2.2)		
hydrochlorothiazide		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
25 Milligram 1 (Days)		
Dosage text (B.4.k.6)		
25 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Blood pressure
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ASPIRATION PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Aspiration pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pneumonia aspiration		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT HAD SEPSIS

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sepsis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Sepsis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
21 Days		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT WAS FEBRILE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pyrexia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pyrexia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
21 Days		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRESUMED ISCHEMIC STROKE PROVOKING SEIZURE WITH SOME RESIDUAL CEREBELLAR DEFICITS INCLUDING DIFFICULTY WITH GAIT, BALANCE, AND SWALLOWING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Seizure
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Seizure

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
194 Hours		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRESUMED ISCHEMIC STROKE PROVOKING SEIZURE WITH SOME RESIDUAL CEREBELLAR DEFICITS INCLUDING DIFFICULTY WITH GAIT, BALANCE, AND SWALLOWING/POSSIBLE CVA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Ischemic stroke
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Ischaemic stroke

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
194 Hours		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNCONSCIOUS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unconscious
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Loss of consciousness

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

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	2021 CCYY	2021 CCYY	20

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
195 Hours		Recovered/resolved with sequelae

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRESUMED ISCHEMIC STROKE PROVOKING SEIZURE WITH SOME RESIDUAL CEREBELLAR DEFICITS INCLUDING DIFFICULTY WITH GAIT, BALANCE, AND SWALLOWING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebellar disorder NOS		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Nervous system disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
194 Hours		Recovered/resolved with sequelae

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRESUMED ISCHEMIC STROKE PROVOKING SEIZURE WITH SOME RESIDUAL CEREBELLAR DEFICITS INCLUDING DIFFICULTY WITH GAIT, BALANCE, AND SWALLOWING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Swallowing difficult		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dysphagia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
194 Hours		Recovered/resolved with sequelae

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRESUMED ISCHEMIC STROKE PROVOKING SEIZURE WITH SOME RESIDUAL CEREBELLAR DEFICITS INCLUDING DIFFICULTY WITH GAIT, BALANCE, AND SWALLOWING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Gait disturbance		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Gait disturbance		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
194 Hours		Recovered/resolved with sequelae

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRESUMED ISCHEMIC STROKE PROVOKING SEIZURE WITH SOME RESIDUAL CEREBELLAR DEFICITS INCLUDING DIFFICULTY WITH GAIT, BALANCE, AND SWALLOWING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Balance difficulty		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Balance disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
194 Hours		Recovered/resolved with sequelae

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable physician (patient's daughter) and other healthcare professional. A 73-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EN1196), intramuscular in the left deltoid on [redacted]2021 as single dose for COVID-19 immunization (Age at vaccination: 73 years). Medical history included dementia mixed vascular and Alzheimer's both from 2016 and ongoing, and hypertension from 2011 and ongoing dislipidemia and prostate cancer. Family history includes dementia with siblings [redacted] but no seizures or strokes. Concomitant medications included nabilone, risperidone (RISPERDAL), and trazodone all taken for agitation from an unspecified start date and ongoing. Patient also received enalapril (VASOTEC) and hydrochlorothiazide (HCT) all for hypertension . The patient previously received the first dose of bnt162b2 (Lot number: Lot EP6017) on [redacted]2021 in the left deltoid as a single dose for COVID-19 immunization. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not have any known allergies. The patient had no other vaccine within four weeks. On [redacted]2021 02:00, the patient had presumed ischemic stroke provoking seizure with some residual cerebellar deficits including difficulty with gait, balance, and swallowing. On [redacted]2021 03:00, the patient was found unconscious for 20 minutes until [redacted]2021 03:20. The patient was sent to the emergency room. Trazodone was reduced. He was not febrile and was doing relatively well. The patient was not admitted and was discharged from the hospital emergency room the same day as he arrived, to get palliative care at home. Ischemic stroke and unconscious were considered as life threatening and all the events on [redacted]2021 had caused disability to the patient. The patient's outcome was recovered with sequala. The patient underwent lab tests and procedures which included blood test: unknown result on an unspecified date and computerized tomogram (CAT scan): no bleed, no mass on [redacted]2021. On the day of the death on [redacted]021, the paramedics were called because the patient had sepsis, was febrile and as the patient wishes were to stay home, they gave him morphine and scopolamine a few times. The patient died at home. They concluded that the death was probably due to medication. The doctor was unsure if the vaccine had a role but wanted to report this event. She is still thankful to Pfizer because she received the vaccine and she feel safer when working. The patient died on [redacted]2021. It was not reported if an autopsy was performed. According to the physician the patient's daughter called stating he likely died of aspiration pneumonia and became septic.

Follow-up [redacted]021): New information received from the same contactable physician (patient's daughter) includes: medical history, concomitant medications, new events (sepsis, febrile, death), event outcome.

Information on the lot/batch number has been requested.

Follow-up [redacted]2021): This is a follow-up report from the same contactable healthcare professional (physician) for the same patient.
New information included: medical history updated, new fatal event pneumonia aspiration, concomitant medication updated, date of death changed, event death deleted.

Follow-up attempts completed. No further information expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The 73-year-old patient had medical history included dementia mixed vascular, Alzheimer's, and hypertension, and was on multiple concomitant medication(s). Based on information available, the ischemic stroke provoking seizure with some residual cerebellar deficits including difficulty with gait, balance, and swallowing were most likely an intercurrent disease, and unlikely causally related to vaccine bnt162b2. Pneumonia aspiration, Sepsis, Pyrexia, Unconscious are considered as intercurrent or underlying conditions which are not related to the suspected drug.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
202[redacted] CCYYMMDD	CAT scan	No bleed, no mass	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood test	unknown result	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Dementia vascular

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
2016 CCYY	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dementia Alzheimer's type	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2016 CCYY	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2011 CCYY	Yes	
Comments (B.1.7.1g)		
chronic		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyslipidemia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		
chronic		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Prostate cancer	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Sepsis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pyrexia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Seizure	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Ischemic stroke	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	Episode name (B.1.7.1a.2) Aspiration pneumonia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a) BNT162B2	
Start date (B.1.8c) 202[redacted] CCYYMMDD	End date (B.1.8e) 202[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	Indication (B.1.8f.2) COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04060632 (2)	Page#15

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04106577 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210512 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-009507513-2104CAN005384(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021 [redacted] CCYYMMDD	2021 [redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

PVI Attachment

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-009507513-2104CAN005384

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
009507513	CA-009507513-2104CAN005384

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MERCK CANADA INC

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1975 [redacted] CCYYMMDD			45 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)
			[redacted]

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	PEMBROLIZUMAB	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 400 Milligram,1 every 6 (Weeks)		
Dosage text (B.4.k.6) 400 milligram, every 6 weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Head and neck cancer metastatic
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 27360 Minutes	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Death	
Source of assessment (B.4.k.18.2) Investigator	**Method of assessment (B.4.k.18.3)** EVCTM	**Result (B.4.k.18.4)** Reasonable possibility
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Sponsor	EVCTM	No reasonable possibility
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Investigator	EVCTM	Reasonable possibility
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lung infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Sponsor	EVCTM	No reasonable possibility
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Investigator	EVCTM	No reasonable possibility
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label dosing	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Sponsor	EVCTM	No reasonable possibility

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Death	
Source of assessment (B.4.k.18.2) Investigator	Method of assessment (B.4.k.18.3) EVCTM	Result (B.4.k.18.4) Reasonable possibility
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Lung infection	
Source of assessment (B.4.k.18.2) Investigator	Method of assessment (B.4.k.18.3) EVCTM	Result (B.4.k.18.4) Reasonable possibility
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Off label dosing	
Source of assessment (B.4.k.18.2) Investigator	Method of assessment (B.4.k.18.3) EVCTM	Result (B.4.k.18.4) Reasonable possibility

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
27360 Minutes		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LUNG INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lung infection		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
12960 Minutes		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OFF LABEL DOSING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Off label dosing		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Off label use		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
86400 Seconds		Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This solicited report was received from a physician regarding to a 45 year old male patient enrolled in a Patient Support Program entitled \"Merck Care Oncology (Bayshore)\" conducted by Bayshore Healthcare Ltd. Information regarding the patient's concomitant therapies, medical history and historical drugs was not provided.

On [redacted]2021, the patient started therapy with pembrolizumab (KEYTRUDA) 400 milligram, every 6 weeks (route of administration, lot # and expiration date were not provided) for head and neck cancer metastatic (off label use).

Follow-up information was received from the patient's common law via Bayshore on [redacted]2021.
On an unknown date (reported as "previously"), the patient was tested for coronavirus disease 2019 (COVID 19), however the result was not provided, and he was vaccinated with an unspecified sars-cov-2 vaccine (reported as COVID 19 vaccine), (dose, frequency, route of administration, indication, lot number and expiration date were not provided). Approximately on [redacted]2021, the patient started experiencing severe shortness of breath despite on oxygen and medications. The physician was notified and thought it was pleural effusion, and said that the patient needed to be drained. They also recommended a chest X-ray which was done on an unspecified date and confirmed lung infection. Since [redacted]2021, the patient was hospitalized with a lung infection. They were not sure if patient would be discharged home or hospice, they were waiting for a PICC line and DNR to be set up. At the reporting time, the outcome of the event was unknown. Therapy with pembrolizumab (KEYTRUDA) was continued. The causality assessment between pembrolizumab (KEYTRUDA), unspecified sars-cov-2 vaccine and lung infection was not provided by the reporter.

Upon internal review, pneumonia was considered to be medically significant.

Follow-up information was received from the physician's assistant via [redacted]2021.
On [redacted]2021, the patient died. The cause of death was not provided. It was not reported if an autopsy was performed. The reporter informed health records and cancelled all appointments. The causality assessment between the patient's death, pembrolizumab (KEYTRUDA) and the unspecified sars-cov-2 vaccine was not provided.
Company Causality Assessment: Based on the limited information currently available for this case, a reasonable possibility to suggest a relationship between the therapy and the reported events of pneumonia and death cannot be established. Additional information regarding concurrent conditions, medical history, diagnostic work ups, clinical course, autopsy information (if done), and outcome for pneumonia is essential for further assessment.

Company Comment- No changes to the KEYTRUDA product safety information are warranted at this time. Merck and Co., Inc., Kenilworth, N.J., USA, known as MSD outside of the US and Canada, continues to monitor the safety profile of KEYTRUDA.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Head and neck cancer metastatic	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	D		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Merck Care Oncology (Bayshore)	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
[redacted]	Other studies

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Anonymized

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Merck Care Oncology (Bayshore)	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
[redacted]	Other studies

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Bayshore Healthcare Ltd.	

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Merck Care Oncology (Bayshore)	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
[redacted]	Other studies

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04111374 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210908 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A382781()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20210906 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A382781

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_04111374 [redacted] CA-AstraZeneca-2021A382781

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 54 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral thrombosis
26.0	Fatigue
26.0	Headache
26.0	Immune thrombocytopenia
26.0	Thrombocytopenia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 1- FIRST DOSE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL BLOOD CLOT/ CEREBRAL THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT)

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Immune thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Immune thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fatigue		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Fatigue		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a 54 year old female patient.

No medical history was reported. No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN), via intramuscular route, for product used for unknown indication on [redacted]2021.

On an unknown date, the patient experienced cerebral blood clot/ cerebral thrombosis (preferred term: Cerebral thrombosis). On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia). On an unknown date, the patient experienced vaccine-induced immune thrombotic thrombocytopenia (vitt) (preferred term: Immune thrombocytopenia). On an unknown date, the patient experienced fatigue (preferred term: Fatigue). On an unknown date, the patient experienced headache (preferred term: Headache).

The family said the patient experienced severe headaches and fatigue in the days that followed after vaccination. She was hospitalized locally and then transferred to the another as her condition worsened. She died of cerebral thrombosis.

The action taken for Covid-19 Vaccine Astrazeneca was not applicable with respect to all the events.

The patient died from the event of cerebral blood clot/ cerebral thrombosis, thrombocytopenia, vaccine-induced immune thrombotic thrombocytopenia (vitt), fatigue and headache on [redacted]2021.

An autopsy was not performed. The cause of death was cerebral blood clot/ cerebral thrombosis, thrombocytopenia, vaccine-induced immune thrombotic thrombocytopenia (vitt), fatigue and headache.

The events were considered serious (death, hospitalised and important medical event).

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca on [redacted]2021 from consumer via spontaneous source: Vaccine Dose, informed as First Dose, vaccination date were added and Patients death date were confirmed.

Follow-up of insignificant information received by AstraZeneca on [redacted]2021 from a consumer as spontaneous source: Additional 2 reporters were added. No other significant information was provided.

Summary of follow-up information received by AstraZeneca/MedImmune 06-SEP-2021: Spontaneous report from canadian health authority via consumer: Reporter Regulatory Authority was added, For suspect indication was added, Events CEREBRAL THROMBOSIS, THROMBOCYTOPENIA was added, For events FATIGUE, HEADACHE seriousness criteria was updated.CAUSE OF DEATH: CEREBRAL BLOOD CLOT/ CEREBRAL THROMBOSIS CAUSE OF DEATH: THROMBOCYTOPENIA CAUSE OF DEATH: VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT) CAUSE OF DEATH: FATIGUE CAUSE OF DEATH: HEADACHE
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Thrombosis (Cerebral thrombosis) in combination with thrombocytopenia (Thrombocytopenia and Immune thrombocytopenia) is listed in the company core date sheet of AZD1222. However, since the events were reported with a fatal outcome, they are considered unlisted. Fatigue and Headache are listed adverse events for AZD1222. However, as the events are reported with the seriousness criteria of fatal, the events are considered unlisted. The patient died 14 days after vaccine administration. The cause of death was cerebral blood clot/ cerebral thrombosis, thrombocytopenia, vaccine-induced immune thrombotic thrombocytopenia (vitt), fatigue and headache. Due to limited information on event onset dates, the baseline health status of the patient before vaccination, details of the events, medical history, concurrent diseases, concomitant medications, risk factors (infection with HIV, hepatitis or H. pylori, leukemia, chemotherapy drugs, radiation therapy, autoimmune diseases such as lupus and rheummatoid arthritis, treatment with heparin, quinine, sulfa-containing antibiotics and anticonvulsants), diagnostic and etiological work-up (physical exam, complete blood profile, viral test, bone marrow biopsy, blood tests including anti-PF4 antibodies, thrombophilia screen, autoimmune screen, infection profile, last known platelet count before vaccine, haematologist review), autopsy report, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

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Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Immune thrombocytopenia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fatigue	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Headache	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210507 CCYYMMDD
	HC Initial Received Date:	20210507 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021498390(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210503 CCYYMMDD	20210503 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021498390

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021498390

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			54 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
SINGLE DOSE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B.4.k.15)**
7 Days	7 Days	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Aneurysm	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Aneurysm	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Comatose	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Comatose	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Intracerebral bleed	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Intracerebral bleed	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Vascular anastomosis	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Vascular anastomosis	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) **Current reaction**

PASSED AWAY UNEXPECTEDLY

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Death

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 7 Days	Reaction last time (B.2.i.7.2) 7 Days	Outcome (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTRACEREBRAL BLEED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Intracerebral bleed
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Cerebral haemorrhage

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 6 Days	Reaction last time (B.2.i.7.2) 6 Days	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COMATOSE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Comatose
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Coma

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 7 Days	Reaction last time (B.2.i.7.2) 7 Days	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

POTENTIAL ANEURISM

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Aneurysm
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Aneurysm

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

AV ANASTOMOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vascular anastomosis
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Vascular anastomosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (reporting for husband). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot number was not reported), via an unspecified route of administration on [redacted]2021 as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the reporter's husband (patient) passed away unexpectedly on [redacted]2021. The patient had a catastrophic intracerebral bleed the morning of [redacted]2021. The patient was comatosed then lost all vital functions on [redacted]2021. There were no prodromes. The patient had no history of hypertension (HTN). There was no explanation. Not a thrombotic event though. There was nothing specific in the bloodwork o[redacted]2021. The reporter stated potential aneurism, AV anastomosis or something third (AS REPORTED). The outcome of the events was unknown. The patient died on [redacted]2021. It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
202[redacted] CCYYMM	Blood test	Nothing specific

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Unknown cause of death

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04124362 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210617 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021493258(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210426 CCYYMMDD	20210610 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021493258

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021493258

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			91 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04124362 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Pulmonary embolism

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) 1ST DOSE, SINGLE DOSE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12) 202[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 202[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 22 Days	**Last period (B.4.k.13.2)** 22 Days	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pulmonary embolism	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pulmonary embolism	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PULMONARY EMBOLISM

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary embolism		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pulmonary embolism		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
22 Days	22 Days	Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer reporting on behalf of the mother.
A 91-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on 19Feb2021 as the first single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was unknown if the patient was pregnant. The patient experienced pulmonary embolism on [redacted]2021. The patient was hospitalized for the event on an unspecified date. Clinical course was as follows: Reporter's 91-year-old mother was vaccinated on [redacted]2021 with her first dose of the Pfizer-Biontech vaccine with no other issues. Twenty-one (21) days later, on [redacted]2021, the first symptoms that something was not right appeared. After being seen by nurses and a doctor, she was admitted to hospital and was treated for a pulmonary embolism with heparin. The reporter was not saying that the vaccine caused the embolism, but the chronology of events left them questioning. The event was reported with fatal outcome. The patient died on an unspecified date in 2021. It was unknown if an autopsy was performed.

Follow-up (10Jun2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Pulmonary embolism		
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**	

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04124362 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-04-06 2:52 PM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: RE: Health Canada Follow-Up Clarification Request

EXTERNAL

Re: Health Canada Follow-Up Clarification Request

Good afternoon Mr. [redacted]

Please allow us first to convey our deepest regrets with the recent loss of your dear grand-mother. We offer you our most sincere condolences during this difficult time of grief.

We are contacting you today to confirm receipt of the adverse event following immunization (AEFI) report submitted to the Canada Vigilance Program on April 2nd, 2021 regarding your grand-mother and the use of the COVID-19 Vaccine.

As the result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified the present individual case safety reports (ICSRs) where clarification is needed in order to complete the case evaluation.

We acknowledge that this is a challenging time to be requesting additional information from you. If it is easier, you may wish to request your grand-mother's physician or other health care provider to assist you, or to submit a reply on your behalf. Any information would be greatly appreciated.

Canada Vigilance Case Number	Clarification Requested
000944395	Would you kindly have any information of the following: - Please provide any information regarding your grand-mother's age, medical history and any concomitant medications. - Please provide any information regarding the COVID-19 vaccine administered. Specifically the trade name, date, and route of administration. - Please provide any information regarding the description of the adverse events. Specifically any investigations, and treatments. - Please provide any information regarding medical confirmation of the cause of death, and any autopsy results if available

May you please kindly respond to both myself, Michelle Séguin: michelle.seguin@canada.ca in addition to the Canada Vigilance COVID-19 Vaccine generic account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca).

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Or, if you prefer, you may fax the requested information to the **Canada Vigilance Program fax at 1-866-678-6789**; please cite **case number 000944395** if replying by this means.

If you require further information within the scope of this request, please do not hesitate to contact me.

We thank you for your time and much appreciated collaboration.

Sincerely,

Michelle Séguin on behalf of:
The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
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A2023000085

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04133082 (8)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220216 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A407153()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210505 CCYYMMDD	20220201 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2) CA-AstraZeneca-2021A407153

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA MC CANADA AZPROD0000	E2B_04133082 [redacted] CA-AstraZeneca-2021A407153

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 52 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Chills
26.0	Clot blood
26.0	Fatigue
26.0	Fever
26.0	Haemorrhage brain
26.0	Headache
26.0	Nausea
26.0	Pain in extremity
26.0	Seizure
26.0	Thrombosis
26.0	Thrombosis with thrombocytopenia syndrome

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 1-First dose		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEIZURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Seizure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Seizure		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VACCINE INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT)

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombosis with thrombocytopenia syndrome
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombosis with thrombocytopenia syndrome

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAIN IN EXTREMITY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pain in extremity
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pain in extremity

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombosis
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Clot blood
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombosis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHILLS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Chills
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Chills

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Fatigue
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Fatigue

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Headache
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Headache

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Nausea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nausea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FATAL BLEED IN HER BRAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Haemorrhage brain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebral haemorrhage

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FEVER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Fever		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pyrexia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAINS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pain		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY). The report concerns a female patient of Unknown ethnic origin (age 52 years).

No medical history was reported. No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. (covid-19 vaccine nrvv ad (chadoxl ncov-19)) (batch number UNKNOWN), via intramuscular route, for product used for unknown indication on [redacted]2021.

On an unknown date, the patient experienced seizure (preferred term: Seizure). On an unknown date, the patient experienced vaccine induced immune thrombotic thrombocytopenia (vitt) (preferred term: Thrombosis with thrombocytopenia syndrome). On an unknown date, the patient experienced pain in extremity (preferred term: Pain in extremity). On an unknown date, the patient experienced thrombosis (preferred term: Thrombosis). On an unknown date, the patient experienced thrombosis. (preferred term: Thrombosis). On an unknown date, the patient experienced chills (preferred term: Chills). On an unknown date, the patient experienced fatigue (preferred term: Fatigue). On an unknown date, the patient experienced headache (preferred term: Headache). On an unknown date, the patient experienced nausea (preferred term: Nausea). On an unknown date, the patient experienced fatal bleed in her brain (preferred term: Cerebral haemorrhage). On an unknown date, the patient experienced fever (preferred term: Pyrexia). On an unknown date, the patient experienced pains (preferred term: Pain). It was reported immune thrombocytopenia and Cerebral haemorrhage. Woman in her 50s was died from a rare blood clot condition after receiving the AstraZeneca-Oxford vaccine and reporter stated that woman was only the second confirmed case of vaccine-induced immune thrombotic thrombocytopenia (VIIT) in the province. Reporter confirms first death linked to AstraZeneca vaccine. The Canadian province reporter reported its first death of a patient from a rare blood clot condition after receiving the AstraZeneca (AZN.L) COVID-19 vaccine, its chief medical officer said. It stated her mom was suffering from fatigue, strong nausea, headache, fever and chills. The symptoms were continuing to get worse a full week after she received her first shot. Patient was died from a rare blood clot condition after receiving the AstraZeneca-Oxford vaccine. It stated her mother was turned away at the emergency room of Hospital last Thursday as her symptoms worsened. The next day the otherwise healthy woman suffered a fatal bleed in her brain. Patient had aches and pains after she received her first dose of the Oxford-AstraZeneca vaccine, but after about a week, things took a turn. She developed a headache that quickly got worse, so bad that her 19 years old daughter insisted they head to the emergency department to get it checked out. They said there was nothing they can do for me. Take some Tylenol, and go to bed and by the next morning, patient was in so much pain she could not get out of bed, she was taken to another hospital, where a CT scan confirmed a blood clot, and she was rushed to the hospital but suffered a seizure on the way. She died three days later, becoming one of three people in Canada who have died from extremely rare but serious blood clots linked to the AstraZeneca vaccine. Laboratory values are available. On an unknown date patient had CT Scan results confirmed blood clot.

The outcome of the event(s) of pains was unknown. The patient died from the event of seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever on an unspecified date.

It is not known whether an autopsy was performed. The cause of death was seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever.

The following events were considered serious due to death: seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever. The following events were considered serious due to important medical event: seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever. The following events were considered non-serious: pains.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a

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for regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The AstraZeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. Product authorized under the interim order.

Summary of follow-up information received by AstraZeneca on 14-MAY-2021 via consumer originating from spontaneous source: New reporter added. Pains and seizure were added as event.

Summary of follow-up information received by AstraZeneca 18-MAY-2021: New reporter added. Events Pains and seizure were added, CT SCAN confirmed a blood clot added from the narrative to the events tab.

Summary of follow-up information received by AstraZeneca 21-JUN-2021: A spontaneous report had been received from a consumer, following information updated: New reporters were added.

Summary of follow-up of insignificant information received by AstraZeneca on 06-JUL-2021: A spontaneous report had been received from a consumer, following information updated: New reporters were added.

Summary of follow-up information received by AstraZeneca on 06-SEP-2021 from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer originating from spontaneous source: Two reporters were added included Regulatory authority and Reference reporter. The serious criteria of events fatal bleed in her brain (PT: Cerebral haemorrhage), chills, fatigue, headache, vaccine-induced immune thrombotic thrombocytopenia (VITT) (PT: Immune thrombocytopenia) and nausea were updated. Outcome of the events chills, fatigue, headache and nausea were updated to fatal. Events of chills, headache, nausea, and fatigue were added as cause of death. Narrative was updated accordingly. Corrected report on 09-SEP-2021: Lab was recoded as CT scan, and result was corrected. Narrative was updated accordingly.

Corrected Report 13-SEP-2021: Case opened for corrections in CCC.

Summary of follow up information received by AstraZeneca 06-SEP-2021 received via a consumer: A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer, Events immune thrombocytopenia and cerebral hemorrhage were added, event fatal bleed in her brain was coded to hemorrhage brain, and pains was coded to pain as per company physician.

Summary of follow up information received by AstraZeneca 21-NOV-2021 received via a consumer: A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer, added events Thrombosis, pain in extremity. Changed event as reported from CT scan confirmed a blood clot to Thrombosis. Seriousness of the events was updated for events immune thrombotic thrombocytopenia (vitt), seizure, fatal bleed in her brain, fatigue, nausea, headache, chills, thrombosis. and fever as death and important medical event. Updated narrative.

Summary of follow up information received by AstraZeneca 01-FEB-2022: A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer. The events immune thrombocytopenia and cerebral haemorrhage were deleted and recoded the event VACCINE INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT) to LLT: Thrombosis with thrombocytopenia syndrome. Narrative was updated.

CAUSE OF DEATH: SEIZURE CAUSE OF DEATH: VACCINE INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT) CAUSE OF DEATH: PAIN IN EXTREMITY CAUSE OF DEATH: THROMBOSIS CAUSE OF DEATH: THROMBOSIS. CAUSE OF DEATH: CHILLS CAUSE OF DEATH: FATIGUE CAUSE OF DEATH: HEADACHE CAUSE OF DEATH: NAUSEA CAUSE OF DEATH: FATAL BLEED IN HER BRAIN CAUSE OF DEATH: FEVER Lab Test #1 : 10011603
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal events of Seizure and Cerebral hemorrhage are not listed in the company core data sheet of AZD1222. Headache, Fatigue, Chills, Pyrexia, Pain in extremity and Nausea is listed in company core data sheet of AZD1222. However, since the events were reported with a fatal outcome, it is considered unlisted. Thrombosis (preferred term: Thrombosis and preferred term: Thrombosis) in combination with Thrombocytopenia (preferred term: Thrombosis with thrombocytopenia syndrom) is listed in the company core data sheet of AZD1222. However, as the events were reported with the seriousness criteria of death, it is considered unlisted. Cerebral hemorrhage, Seizure and Headache could be in association with each other. Cerebral hemorrhage could further be in association with the combination of thrombosis and thrombocytopenia. Due to limited information on baseline health condition before vaccination, relevant family and medical history (head trauma, stroke, cardiovascular disease, hypertension, bblood vessel abnormalities, brain tumor, deep venous thrombosis, neoplastic disease, thrombophilia), concurrent conditions (metabolic or infectious diseases, head trauma, atherosclerosis), concomitant medications, further clarification of the events, clinical course, treatment and interventions, risk factor (smoking, alcohol or illicit drugs intake), detailed etiological and diagnostic workup (physical examination, neurological evaluation, complete blood profile including coagulation panel, complete report of computerized tomography performed, electroencephalogram, lumbar puncture with cerebrospinal fluid analysis, D dimer test, cardiac assessment, echocardiogram, other relevant imaging studies, complete autopsy report), the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	CT scan	Confirmed a blood clot	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

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Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Seizure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis with thrombocytopenia syndrome	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pain in extremity	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chills	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fatigue	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Headache	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Nausea	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	Episode name (B.1.7.1a.2) Haemorrhage brain	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	Episode name (B.1.7.1a.2) Fever	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

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Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	PRIVACY	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
PRIVACY

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Turkey	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

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UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Bulgaria	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

PRIVACY

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

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Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	
Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) UNKNOWN	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) UNKNOWN
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c) PRIVACY			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Bulgaria	**Qualification** (A.2.1.4)	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	
Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) UNKNOWN	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) UNKNOWN
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c) PRIVACY			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4)	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	
Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b)	**Reporter middle name** (A.2.1.1c)	**Reporter family name** (A.2.1.1d) Confidential
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

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Canada Vigilance AER#:	E2B_04133082 (8)	Page#13

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Turkey	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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SUSPECT ADVERSE REACTION REPORT

CIOMS FORM

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year
	Canada				52	F	??	??	??

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Seizure (10039906) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Thrombosis with thrombocytopenia syndrome (10086158) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Pain in extremity (10033425) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Thrombosis (10043607) [v.26.0] - Fatal
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [X] PATIENT DIED
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- [ ] INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [X] OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML(chadox1-s [recombinant])(SOLUTION INTRAMUSCULAR)(chadox1-s [recombinant]),UNKNOWN

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
Dose 1-First dose

16. ROUTE(S) OF ADMINISTRATION
Intramuscular

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATION(S) FOR USE
Product used for unknown indication[10070592] [v.26.0]

18. THERAPY DATES(from/to)
21/APR/2021 -

19. THERAPY DURATION

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

Concomitant Drug Not Reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
ASTRAZENECA
Canada

24b. MFR. CONTROL NO.
CA-AstraZeneca-2021A407153
Log No : 2021A407153

24c. DATE RECEIVED BY MANUFACTURER
16/FEB/2022

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
16/FEB/2022

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP

ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML.
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML.
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML.

Company Remarks (Sender's comments) :
Fatal events of Seizure and Cerebral hemorrhage are not listed in the company core data sheet of AZD1222. Headache, Fatigue, Chills, Pyrexia, Pain in extremity and Nausea is listed in company core data sheet of AZD1222. However, since the events were reported with a fatal outcome, it is considered unlisted. Thrombosis (preferred term: Thrombosis and preferred term: Thrombosis) in combination with Thrombocytopenia (preferred term:

Cont...

Cont... = Continuation attached sheet(s)

DRAFT

ASTRAZENECA
ATIA-19(1)

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A407153**

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Thrombosis (10043607) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Chills (10008531) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Fatigue (10016256) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Headache (10019211) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Nausea (10028813) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Cerebral haemorrhage (10008111) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Pyrexia (10037660) [v.26.0] - Fatal
Protocol relatedness:
As per reporter:
As per company:

Pain (10033371) [v.26.0] - Unknown
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Fatal

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY). The report concerns a female patient of Unknown ethnic origin (age 52 years).

No medical history was reported. No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN), via intramuscular route, for product used for unknown indication on [redacted]021.

On an unknown date, the patient experienced seizure (preferred term: Seizure). On an unknown date, the patient experienced vaccine induced immune thrombotic thrombocytopenia (vitt) (preferred term: Thrombosis with thrombocytopenia syndrome). On an unknown date, the patient experienced pain in extremity (preferred term: Pain in extremity). On an unknown date, the patient experienced thrombosis (preferred term: Thrombosis). On an unknown date, the patient experienced thrombosis. (preferred term: Thrombosis). On an unknown date, the patient experienced chills (preferred term: Chills). On an unknown date, the patient experienced fatigue (preferred term: Fatigue). On an unknown date, the patient experienced headache (preferred term: Headache). On an unknown date, the patient experienced nausea (preferred term: Nausea). On an unknown date, the patient experienced fatal bleed in her brain (preferred term: Cerebral haemorrhage). On an unknown date, the patient experienced fever (preferred term: Pyrexia). On an unknown date, the patient experienced pains (preferred term: Pain). It was reported immune thrombocytopenia and Cerebral haemorrhage. Woman in her 50s was died from a rare blood clot condition after receiving the AstraZeneca-Oxford vaccine and reporter stated that woman was only the second confirmed case of vaccine-induced immune thrombotic thrombocytopenia (VIIT) in the province. Reporter confirms first death linked to AstraZeneca vaccine. The Canadian province reporter reported its first death of a patient from a rare blood clot condition after receiving the AstraZeneca (AZN.L) COVID-19 vaccine, its chief medical officer said. It stated her mom was suffering from fatigue, strong nausea, headache, fever and chills. The symptoms were continuing to get worse a full week after she received her first shot. Patient was died from a rare blood clot condition after receiving the AstraZeneca-Oxford vaccine. It stated her mother was turned away at the emergency room of Hospital last Thursday as her symptoms worsened. The next day the otherwise healthy woman suffered a fatal bleed in her brain. Patient had aches and pains after she received her first dose of the Oxford-AstraZeneca vaccine, but after about a week, things took a turn. She developed a headache that quickly got worse, so bad that her 19 years old daughter insisted they head to the emergency department to get it checked out. They said there was nothing they can do for me. Take some Tylenol, and go to bed and by the next morning, patient was in so much pain she could not get out of bed, she was taken to another hospital, where a CT scan confirmed a blood clot, and she was rushed to the hospital but suffered a seizure on the way. She died three days later, becoming one of three people in Canada who have died from extremely rare but serious blood clots linked to the AstraZeneca vaccine. Laboratory values are available. On an unknown date patient had CT Scan results confirmed blood clot.

The outcome of the event(s) of pains was unknown. The patient died from the event of seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever on an unspecified date.

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A407153**

It is not known whether an autopsy was performed. The cause of death was seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever.

The following events were considered serious due to death: seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever. The following events were considered serious due to important medical event: seizure, vaccine induced immune thrombotic thrombocytopenia (vitt), pain in extremity, thrombosis, thrombosis., chills, fatigue, headache, nausea, fatal bleed in her brain and fever. The following events were considered non-serious: pains.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The AstraZeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. Product authorized under the interim order.

Summary of follow-up information received by AstraZeneca on 14-MAY-2021 via consumer originating from spontaneous source: New reporter added. Pains and seizure were added as event.

Summary of follow-up information received by AstraZeneca 18-MAY-2021: New reporter added. Events Pains and seizure were added, CT SCAN confirmed a blood clot added from the narrative to the events tab.

Summary of follow-up information received by AstraZeneca 21-JUN-2021: A spontaneous report had been received from a consumer, following information updated: New reporters were added.

Summary of follow-up of insignificant information received by AstraZeneca on 06-JUL-2021: A spontaneous report had been received from a consumer, following information updated: New reporters were added.

Summary of follow-up information received by AstraZeneca on 06-SEP-2021 from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer originating from spontaneous source: Two reporters were added included Regulatory authority and Reference reporter. The serious criteria of events fatal bleed in her brain (PT: Cerebral haemorrhage), chills, fatigue, headache, vaccine-induced immune thrombotic thrombocytopenia (VITT) (PT: Immune thrombocytopenia) and nausea were updated. Outcome of the events chills, fatigue, headache and nausea were updated to fatal. Events of chills, headache, nausea, and fatigue were added as cause of death. Narrative was updated accordingly. Corrected report on 09-SEP-2021: Lab was recoded as CT scan, and result was corrected. Narrative was updated accordingly.

Corrected Report 13-SEP-2021: Case opened for corrections in CCC.

Summary of follow up information received by AstraZeneca 06-SEP-2021 received via a consumer: A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer, Events immune thrombocytopenia and cerebral hemorrhage were added, event fatal bleed in her brain was coded to hemorrhage brain, and pains was coded to pain as per company physician.

Summary of follow up information received by AstraZeneca 21-NOV-2021 received via a consumer: A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer, added events Thrombosis, pain in extremity. Changed event as reported from CT scan confirmed a blood clot to Thrombosis. Seriousness of the events was updated for events immune thrombotic thrombocytopenia (vitt), seizure, fatal bleed in her brain, fatigue, nausea, headache, chills, thrombosis. and fever as death and important medical event. Updated narrative.

Summary of follow up information received by AstraZeneca 01-FEB-2022: A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer. The events immune thrombocytopenia and cerebral haemorrhage were deleted and recoded the event VACCINE INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT) to LLT: Thrombosis with thrombocytopenia syndrome. Narrative was updated.

CAUSE OF DEATH: SEIZURE CAUSE OF DEATH: VACCINE INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT) CAUSE OF DEATH: PAIN IN EXTREMITY CAUSE OF DEATH: THROMBOSIS CAUSE OF DEATH: THROMBOSIS. CAUSE OF DEATH: CHILLS CAUSE OF DEATH: FATIGUE CAUSE OF DEATH: HEADACHE CAUSE OF DEATH: NAUSEA CAUSE OF DEATH: FATAL BLEED IN HER BRAIN CAUSE OF DEATH: FEVER Lab Test #1 : 10011603
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Company Remarks (Sender's comments) (Cont...)

Thrombosis with thrombocytopenia syndrom) is listed in the company core data sheet of AZD1222. However, as the events were reported with the seriousness criteria of death, it is considered unlisted. Cerebral hemorrhage, Seizure and Headache could be in association with each other. Cerebral hemorrhage could further be in association with the combination of thrombosis and thrombocytopenia. Due to limited information on baseline health condition before vaccination, relevant family and medical history (head trauma, stroke, cardiovascular disease, hypertension, blood vessel abnormalities, brain tumor, deep venous thrombosis, neoplastic disease, thrombophilia), concurrent conditions (metabolic or infectious diseases, head trauma, atherosclerosis), concomitant medications, further clarification of the events, clinical course, treatment and interventions, risk factor (smoking, alcohol or illicit drugs intake), detailed etiological and diagnostic workup (physical examination, neurological evaluation, complete blood profile including coagulation panel, complete report of computerized tomography performed, electroencephalogram, lumbar puncture with cerebrospinal fluid analysis, D dimer test, cardiac assessment, echocardiogram, other relevant imaging studies, complete autopsy report), the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No. : 1
Drug : VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML(chadox1-s [recombinant])(SOLUTION INTRAMUSCULAR)(chadox1-s [recombinant])

Causality

1) Seizure (10039906) [v.26.0]

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Continuation Sheet for CIOMS report **Mfr. Control No. :CA-AstraZeneca-2021A407153**

Action(s) taken with drug : Not Applicable

Additional information (continuation)

Lab Result :

Test name	Test date	Test result	Normal value	Classification
10011603		Confirmed a blood clot		

Initial Reporter (Cont...)

PRIVACY UNKNOWN CANADIAN HEALTH AUTHORITY
UNKNOWN
UNKNOWN, UNKNOWN UNKNOWN
Canada

DRAFT

DRAFT

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04135542 (3)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210706 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021523184(4)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	20210705 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021523184

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Pfizer PFIZERINC	CA-PFIZER INC-2021523170 CA-PFIZER INC-2021523184

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			72 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Myocardial infarct

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
22336 Minutes	22336 Minutes	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocardial infarct	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Myocardial infarct	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vaccination site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vaccination site pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) SERTRALINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) sertraline hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Depression
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ATORVASTATIN	
Active Substance names (B.4.k.2.2) atorvastatin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Hypercholesterolemia
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MYOCARDIAL INFARCT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Myocardial infarct		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
22336 Minutes	22336 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAIN AT INJECTION SITE AFTER RECEIVING THE VACCINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Vaccination site pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Vaccination site pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BAD HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
14 Days	14 Days	Unknown	

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Canada Vigilance AER#:	E2B_04135542 (3)	Page#7

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable physician through a Pfizer sales representative. A 72-year old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, batch/lot number unknown) on an [redacted]2021 as 1ST DOSE, SINGLE for COVID-19 immunization (Age at vaccination: 72 years). Medical history included blood pressure (controlled with medication), sleep apnea (compliant with her CPAP), Renal Chronic Disease (Creatinine was well maintained at 135), depression, hypercholesterolemia, high cholesterol and Atherosclerosis. Concomitant medications included sertraline hydrochloride (ZOLOFT) taken for depression; atorvastatin (LIPITOR) taken for hypercholesterolemia. On [redacted]021, the reporter stated that the patient passed away from a Myocardial Infarct on [redacted]2021 at 12:16AM. She had been stable for a very long time. Her sugar blood level was perfect. Reporter confirmed that on the morning of the [redacted]2021, patient had a bad headache but nothing too worrying, with no other symptoms. Patient had pain at injection site after receiving the vaccine on [redacted]2021, but had recovered. CPR was done on patient but reporter did not know if patient was already dead when the ambulance arrived. Outcome of the event myocardial infarction was fatal while outcome of the event vaccination site pain was recovered on an unspecified date. Outcome of the event headache was unknown. The patient died on [redacted]2021 from a Myocardial Infarct. It was not reported if an autopsy was performed.

Information on the batch number has been requested.

Follow-up [redacted]2021): New information from the same contactable physician as part of follow-up activities performed by the DSU included: patient's age, age at vaccination, start date, stop date, medical history, concomitant medications, reaction data (events: myocardial infarction, vaccination site pain and headache), event onset, laboratory data, outcome of the event and death details.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Follow-up [redacted]021): This is a follow-up report to notify that the case AER 2021523184 and AER 2021523170 are duplicates. All subsequent follow-up information will be reported under manufacturer report number AER 2021523184. The new information reported from a contactable physician included: added medical history.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Amendment: This follow-up report was submitted to amend previously reported information: patient gender was updated to female.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Event myocardial infarction represents an intercurrent medical condition and unrelated to bnt162b2. The underlying disease may provide an alternative cause.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Blood glucose	perfect	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Creatinine	well maintained at 135	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Sleep apnea	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)
compliant with her CPAP

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Chronic renal impairment

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)
Creatinine was well maintained at 135

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Blood pressure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)
controlled with medication

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	High cholesterol	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Atherosclerosis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Depression	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypercholesterolemia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	CPAP	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Myocardial infarct	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)			
Start date (B.1.8c)		End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)		Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)		Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04154512 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210623 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021541037(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210506 CCYYMMDD	20210616 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021541037

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021541037

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			58 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)** Unknown	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) 1ST DOSE, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 202[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 202[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 6 Days	**Last period (B.4.k.13.2)** 6 Days	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Sudden death, cause unknown	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Sudden death, cause unknown	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ZOPICLONE	
Active Substance names (B.4.k.2.2) zopiclone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) JANUVIA	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) B12 [CYANOCOBALAMIN]	
Active Substance names (B.4.k.2.2) CYANOCOBALAMIN		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) METFORMIN	
Active Substance names (B.4.k.2.2) metformin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) GLICLAZIDE	
Active Substance names (B.4.k.2.2) gliclazide		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ATORVASTATIN CALCIUM	
Active Substance names (B.4.k.2.2) atorvastatin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ACETYLSALICYLIC ACID	
Active Substance names (B.4.k.2.2) acetylsalicylic acid		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) CALCIUM [CALCIUM CARBONATE]	
Active Substance names (B.4.k.2.2) CALCIUM CARBONATE		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN D	
Active Substance names (B.4.k.2.2) vitamin d		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Sudden death, cause unknown		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Sudden death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 6 Days	Reaction last time (B.2.i.7.2) 6 Days	Outcome (B.2.i.8) Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable physician.

A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular (at the age of 58-years-old), administered in Arm Right on [redacted]2021 (Lot Number: Unknown) as 1st dose, single for COVID-19 immunization. Medical history included s / p ruptured aneurysm, vascular dementia, old MCAS infarction (as reported), Heart failure (LVEF 23%), atherosclerotic heart disease old infarction (subclavian and carotid), diffuse MVAS (subclavian and carotid, as reported), and diabetes. Concomitant medications included zopiclone, sitagliptin phosphate (JANUVIA [SITAGLIPTIN PHOSPHATE]), cyanocobalamin, metformin, gliclazide, atorvastatin, aspirin, calcium carbonate, vitamin D: all taken for an unspecified indication, start and stop dates were not reported. The 58-year-old patient very ill (s / p ruptured aneurysm, vascular dementia, atherosclerotic heart disease old infarction, cardiac insufficiency (left ventricular Ejection Fraction LVEF 23%), diffuse atherosclerotic vascular disease (subclavian and carotid), diabetes) who received her 1st dose on [redacted] and was found dead in her bed on [redacted]021. Her body was found in her bed, semi sitting on the edge of the bed and body thrown backwards, suggesting sudden death. The family kept the reporter informed 1 week later and no autopsy was done. The patient died on [redacted]2021. An autopsy was not performed.

Facility where the most recent COVID-19 vaccine was administered was in a Nursing Home/Senior Living Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19.

Information on the lot/batch number has been requested.

Follow-up (16Jun2021): This follow-up is being submitted to notify that the batch/lot number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Death of unknown cause is assessed related as a cautionary measure and for reporting purposes. The underlying disease may provide an alternative cause.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
The follow-up information received does not alter the previous company clinical evaluation.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Aneurysm ruptured	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Vascular dementia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Infarction	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart failure with reduced ejection fraction	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Atherosclerotic cardiovascular disease	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		
diffuse atherosclerotic vascular disease (subclavian and carotid)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Physician
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

ATIA - 19(1)

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Canada Vigilance AER#:	E2B_04166359 (4)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210823 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021547048(5)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	20210816 CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021547048

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021547048

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			65 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04166359 (4)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Atrial fibrillation
26.0	Blood pressure dropped
26.0	Cardiac valve disease
26.0	Heart attack
26.0	Hemorrhagic stroke
26.0	Pulmonary edema
26.0	Septic shock
26.0	Short of breath
26.0	Vaccination site pain

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**

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21 Days	21 Days	1 Days
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Atrial fibrillation	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Atrial fibrillation	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood pressure decreased	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Blood pressure decreased	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cardiac valve disease	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cardiac valve disease	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Heart attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pain in arm	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pain in arm	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulmonary edema	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulmonary edema	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Septic shock	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Septic shock	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Short of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Short of breath	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ACETYLSALICYLIC ACID	
Active Substance names (B.4.k.2.2) acetylsalicylic acid		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) 81 daily, 1x/day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	BACLOFEN	
Active Substance names (B.4.k.2.2)		
baclofen		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
q.i.d		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) BISOPROLOL	
Active Substance names (B.4.k.2.2) bisoprolol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 5 Milligram 1 (Days)		
Dosage text (B.4.k.6) 5 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CLONAZEPAM	
Active Substance names (B.4.k.2.2)		
clonazepam		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
0.25 At sleep time (h.s)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) COAL TAR/RESORCINOL MONOACETATE	
Active Substance names (B.4.k.2.2) coal tar resorcinol monoacetate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FUROSEMIDE/POTASSIUM CHLORIDE	
Active Substance names (B.4.k.2.2) potassium chloride furosemide		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 40 Milligram 1 (Days)		
Dosage text (B.4.k.6) 40 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) METOCLOPRAMIDE	
Active Substance names (B.4.k.2.2) metoclopramide		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 10 Milligram,3 every 1 (Days)		
Dosage text (B.4.k.6) 10 mg, 3x/day and h.s		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METRONIDAZOLE BENZOATE	
Active Substance names (B.4.k.2.2)		
metronidazole benzoate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MORPHINE	
Active Substance names (B.4.k.2.2)		
morphine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
10 Milligram,3 every 1 (Days)		
Dosage text (B.4.k.6)		
10 mg, 3x/day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) NABILONE	
Active Substance names (B.4.k.2.2) nabilone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 2 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6) 2 mg, 2x/day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	TRANSDERMAL NICOTINE PATCH	
Active Substance names (B.4.k.2.2) nicotine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) DILANTIN [PHENYTOIN]	
Active Substance names (B.4.k.2.2) PHENYTOIN		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 50 Milligram,3 every 1 (Days)		
Dosage text (B.4.k.6) 50 mg, 3x/day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PRAMIPEXOLE DIHYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
pramipexole dihydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
.5 Milligram 1 (Days)		
Dosage text (B.4.k.6)		
0.5 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) PREGABALIN	
Active Substance names (B.4.k.2.2) pregabalin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 300 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6) 300 mg, 2x/day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ALTACE	
Active Substance names (B.4.k.2.2)		
ramipril		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
2.5 UNK, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ROSUVASTATIN CALCIUM	
Active Substance names (B.4.k.2.2)		
rosuvastatin calcium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
5 Milligram 1 (Days)		
Dosage text (B.4.k.6)		
5 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) SENOKOT	
Active Substance names (B.4.k.2.2) sennosides		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 00026158 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	TIOTROPIUM BROMIDE	
Active Substance names (B.4.k.2.2)		
tiotropium bromide		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	TRAZODONE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
trazodone hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
200 Milligram		
Dosage text (B.4.k.6)		
200 mg H.S		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) XARELTO	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	LOVENOX [LEVOFLOXACIN]	
Active Substance names (B.4.k.2.2)		
LEVOFLOXACIN		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readmission? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
21 Days	21 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ISCHEMIC MITRAL VALVE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cardiac valve disease

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MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Cardiac valve disease		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 21 Days	Reaction last time (B.2.i.7.2) 21 Days	Outcome (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD PRESSURE STARTED TO DROP/BLOOD PRESSURE DROPPED (TO 60)

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Blood pressure decreased		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Blood pressure decreased		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 21 Days	Reaction last time (B.2.i.7.2) 21 Days	Outcome (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RUPTURED HEMORRHAGIC STROKE

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Hemorrhagic stroke		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Haemorrhagic stroke		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 21 Days	Reaction last time (B.2.i.7.2) 21 Days	Outcome (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ATRIAL FIBRILLATION

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Atrial fibrillation		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Atrial fibrillation		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 21 Days	Reaction last time (B.2.i.7.2) 21 Days	Outcome (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEPTIC SHOCK

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Septic shock		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Septic shock		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 21 Days	Reaction last time (B.2.i.7.2) 21 Days	Outcome (B.2.i.8) Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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ACUTELY SHORT OF BREATH WITH PULMONARY EDEMA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary edema		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pulmonary oedema		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
2 Days	2 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HER ARM GOT SORE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pain in arm		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pain in extremity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ACUTELY SHORT OF BREATH WITH PULMONARY EDEMA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Short of breath		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
2 Days	2 Days	Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (the son) and a contactable physician. A 65-year-old female patient received bnt162b2, dose 1 via an intramuscular route of administration on [redacted]2021 (Batch/Lot number was not reported) as dose 1, single for covid-19 immunization (at the age of 65-year-old). Medical history included cerebrovascular accident (a few strokes in the past), seizure, encephalomalacia from 2018, chronic obstructive pulmonary disease from Dec2016, postural hypotension (uses Florine! as needed), fibromyalgia, neurogenic bladder, peripheral arterial disease, left internal carotid stenosis from 2016 (50-69%), pulmonary fibrosis from 2016 (patient persistently Shortness of breath cough in late 2016), peripheral neuropathy, post menopausal osteoporosis with high fracture risk (taking prilia & 20001U daily), coronary artery disease(CAD), glaucoma right eye (has had surgery), endometrial cancer (2 surgeries), bilateral cataract, blood clot (in the leg or lung?), allergy to antibiotics, is current smoker and handicapped (walker and wheel chair), onset was 10 years ago. Concomitant medications included acetylsalicylic acid (ASPIRIN 81); baclofen; bisoprolol; clonazepam; coal tar, resorcinol monoacetate (BREA); furosemide, potassium chloride (LASIX + K); metoclopramide; metronidazole benzoate (FLAGYL S); morphine; nabilone; nicotine (TRANSDERMAL SYSTEM); phenytoin (DILANTIN), pramipexole dihydrochloride (MIRAPEX), pregabalin (LYRICA CR), ramipril (ALTACE), rosuvastatin calcium (CRESTOR), sennoside a +b (SENOKOT), tiotropium bromide (SPIRIVA RESPIMAT), trazodone hydrochloride; rivaroxaban (XARELTO), levofloxacin (LOVENOX), all taken for an unspecified indication, start and stop date were not reported. Right after she received her vaccine, her arm got sore on [redacted]2021. The patient experienced acutely short of breath with pulmonary edema on [redacted]2021; blood pressure dropped, heart attack, ischemic mitral valve on, ruptured hemorrhagic stroke, atrial fibrillation and septic shock on [redacted]2021. 6-7 hours later [redacted]2021), her blood pressure started to drop. [redacted]2021 her blood pressure dropped to 60 and she was rushed into the hospital where she fell into a comma and passed away. The reporter mentioned that she was under a lot of medication but did not have the complete list at the time he reported. AE required visit to emergency room. Reporter said he will contact the pharmacy for the complete list for when we call back for F/U. All the reported events were considered serious because caused the death, hospitalized and life-threatening. Course of the event. Myocardial infarction with ischemic mitral valve, ruptured hemorrhagic stroke, atrial fibrillation and septic shock. The patient is a 65-year-old woman admitted on [redacted]2021 with a non-ST elevation MI. She was seen by Internal Medicine at 24 hours and the plan was for angiography, but she was too short of breath to lay flat for this procedure in the first few days. Around day 4, she became acutely short of breath with pulmonary edema and came to the ICU. She required BiPAP and then intubation. Echocardiogram revealed significant mitral valve regurgitation with likely ischemic injury. The patient did have a somewhat poor baseline with previous strokes and residual deficits, decreased cognition with a MOCA of 12/30 and percutaneous endoscopic gastrostomy (PEG) tube requirement for eating at home with a question of possible pulmonary fibrosis. As such, her prognosis was presented to her family as quite poor. It was not clear that her husband really understood most of what was going on. He had asked for things like a heart transplant and blood transfusions to treat this. He seemed to think that all of this was related to receiving a Pfizer vaccine, and in fact, the physician thinks the family has reached out to report this to Pfizer. The physician did review the situation with the cardiologist reading her echo, who felt this was a very clearly ischemic problem and did not seem compatible, at least for the echo findings, with myocarditis, which has been reported with that vaccine. The patient went on to have further complications including atrial fibrillation and septic shock, growing bacillus in sputum and urine. In the last 48 hours, the patient did deteriorate neurologically. There were significant changes to her pupils despite the heavy sedation she was on. we were able to get a Computerized Tomography (CT) scan showing a large hemorrhagic stroke. She continued to deteriorate and passed in the morning of [redacted]2021. Her husband was made well aware of all of these issues and was able to see her. The physician thought he simply had a hard time coping with the loss of his wife, which is very much understandable. The patient underwent lab tests and procedures which included alanine aminotransferase normal: 46 on [redacted]2021, blood bicarbonate: 20 on [redacted]2021, blood creatinine: 57 on [redacted]2021 and [redacted]2021, blood potassium: 3.4 on [redacted]021, 3.4 on [redacted]2021 and 0.9 on [redacted]2021, blood pressure measurement: dropped and 130/90 on [redacted]2021, blood sodium: 137 on [redacted]2021, blood urea: 4 on [redacted]2021, electrocardiogram: no st elevation inferiorly on [redacted]2021 and [redacted]2021, electrocardiogram: there is some inferior st elevation now on [redacted]2021, haemoglobin: 156 on [redacted]2021 and [redacted]2021, pulse: 140 (her pulse was sinus tachycardic), 120 (after a dose of metoprolol) on [redacted]2021 and 140 and 70 on [redacted]2021, gamma-glutamyl transferase: 205 on [redacted]2021, MoCA: 12/30 on [redacted]2021, Positive end expiratory pressure (PEEP): 8 and 12 on [redacted]2021, Mean cell volume: 100 on [redacted]2021, platelet count: 403 on [redacted]2021 and [redacted]2021, fever: 37.8 on [redacted]2021, respiratory rate: 30 on [redacted]2021 (after a dose of metoprolol), SARS-CoV-2 test: Negative on [redacted]2021, troponin: packed at 1.8 on [redacted]2021, white blood cell count: 403 on [redacted]2021 and 20 on [redacted]2021 and X-rays: bilateral infiltrates on [redacted]2021. The patient died on [redacted]2021. It was unknown if the autopsy was performed. The clinical outcome for the events was fatal.

Follow-up [redacted]2021 and [redacted]2021): New information was received from the same contactable consumer (patient's son): event heart attack was added, event details and clinical course added.

Follow-up [redacted]2021): The following information was received from a contactable physician via fax: new adverse events causing patient's death, medical history concomitant medications course of the event.
The report is now medically confirmed.

Follow up information has been requested. Information about lot number has been requested.

Follow-up (13-JUL-2021): the following information was received from the same contactable consumer (patient's husband) that included: updated death date, adverse event, route of administration, medical history and clinical course.

Follow-up (16Aug2021): This follow-up is being submitted to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

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Sender's comments (B.5.4)

Based on the information provided by the reporter, it appears unlikely that subject vaccine contributed to the myocardial infarction and other events. The reported events likely represent intercurrent medical conditions in this elderly patient. There is limited information provided in this report. This case will be reassessed upon receipt of follow-up information.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	ALT normal	46	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Bicarbonate	20	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Blood pressure	130/90	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	BUN	4	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Creatinine	57	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	ECG	no ST elevation inferiorly	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Fever	37.8	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Hemoglobin	156	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Investigation NOS	205	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Mean cell volume	100	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Platelet count	403	

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Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Potassium	3.4	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
202[redacted] CCYYMMDD	Pulse rate	120	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Pulse rate	140	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Respiratory rate	30	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Respiratory rate	30	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Sodium	137	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Troponin	1.8	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	WBC	403	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	COVID-19 virus test	negative	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Creatinine	57	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	ECG	non-ST elevation	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	ECG	There is some inferior ST elevation now	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

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			No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Hemoglobin	**Test result** (B.3.1d) 156	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Investigation NOS	**Test result** (B.3.1d) 12	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 202[redacted] CCYYMMDD	**Test name** (B.3.1c) Investigation NOS	**Test result** (B.3.1d) 12/30	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Investigation NOS	**Test result** (B.3.1d) 8	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Platelet count	**Test result** (B.3.1d) 403	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Potassium	**Test result** (B.3.1d) 0.9	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Potassium	**Test result** (B.3.1d) 3.4	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 202[redacted] CCYYMMDD	**Test name** (B.3.1c) Pulse rate	**Test result** (B.3.1d) 140	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Pulse rate	**Test result** (B.3.1d) 70	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) WBC	**Test result** (B.3.1d) 20	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) X-ray	**Test result** (B.3.1d) bilateral infiltrates	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) Yes
Test date (B.3.1b)	**Test name** (B.3.1c) Blood pressure	**Test result** (B.3.1d) dropped: 60	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No

Results of tests and procedures (B.3.2)

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Troponin [redacted]-2021):peaked at 1.8
Heart rate [redacted]2021):her pulse was sinus tachycardic
Heart rate [redacted]2021):. After a dose of Metoprolol
Respiratory rate [redacted]2021):. After a dose of Metoprolol
X-ray [redacted]2021):bilateral infiltrates

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Stroke	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
a few strokes in the past		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Seizures	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Encephalomalacia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
2018 CCYY		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	COPD	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
201612 CCYYMM		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Postural hypotension	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
uses Florine! as needed (prn)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fibromyalgia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Neurogenic bladder	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Peripheral arterial disease	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Carotid artery stenosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2016 CCYY		
Comments (B.1.7.1g)		
50-69%		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pulmonary fibrosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2016 CCYY		
Comments (B.1.7.1g)		
patient persistently Shortness of breath (SOB)/cough in late 2016,		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Peripheral neuropathy	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
bilateral lower limbs		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Osteoporosis postmenopausal	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
taking prilia & 2000IU daily		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Coronary artery disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2020 CCYY		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Glaucoma surgery	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Endometrial cancer	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
2 surgeries		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Bilateral cataracts	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
in the leg or lung?		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Allergy to antibiotic	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
to antibiotics		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Smoker	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
2 packs/day (feb2021)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Handicap	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		
onset: 10 years		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Short of breath	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Vaccination site pain	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac valve disease	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemorrhagic stroke	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Atrial fibrillation

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Septic shock	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pulmonary edema	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Blood pressure dropped	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

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Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Physician
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04170000 (3)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211125 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A431685()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210511 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211121 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**	
	Company number (A.1.10.2) CA-AstraZeneca-2021A431685	

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC CANADA MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B 04170000 [redacted] CA-AstraZeneca-2021A431685

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 40 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04170000 (3)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral haemorrhage

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral haemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a male patient of Unknown ethnic origin (age 40 years).

No medical history was reported. No concomitant products were reported.

The patient received AstraZeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. (covid-19 vaccine nrvv ad (chadox1 ncov-19)) 0.5 ml, via intramuscular route, for covid-19 immunisation on an unknown date.

On [redacted]2021, the patient experienced cerebral haemorrhage (preferred term: Cerebral haemorrhage).

The action taken for AstraZeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable.

The patient died from the event of cerebral haemorrhage on an unspecified date.It is not known whether an autopsy was performed. The cause of death was cerebral haemorrhage.

The outcome of the event cerebral haemorrhage was died.

The following event was considered serious due to death and important medical event: cerebral haemorrhage.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of Significant follow-up information received by AstraZeneca/Medimmune date-25-MAY-2021 via Consumer from spontaneous: and In the follow-up Seriousness criteria Dead was added. Age of the patient was added.

Follow-up of insignificant information received by AstraZeneca/Medimmune on 02-JUN-2021 (received via database reconciliation) via consumer: A spontaneous report was received from a consumer. No new information was updated.

Summary of follow-up information received by AstraZeneca on 11-OCT-2021 via consumer: New reporter regulatory authority was added, Other reporter is replaced with Reference reporter, Dose as used was added, Route of administration was updated, Indication was updated, Disease was updated, ethnic origin was updated to unknown, event verbatim BRAIN HEMORRHAGE was updated to CEREBRAL HAEMORRHAGE, event onset date was removed. Corrected report 25-OCT-2021: Batch number captured as unknown was removed and kept as blank.

Summary of follow-up information received by AstraZeneca on 21-Nov-2021: A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer : additional reporter as other was added, event onset date as 10-MAY-2021 was added for event cerebral haemorrhage and narrative was updated.CAUSE OF DEATH: CEREBRAL HAEMORRHAGE
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Cerebral hemorrhage is not listed in the company core sheet for AZD1222. Due to limited information on baseline health condition before the vaccination, exact onset date of vaccination, clinical course of the event, concurrent diseases (such as hypertension, diabetes mellitus, infections, coagulation disorders), relevant medical and family history, concomitant medications (aspirin, anticoagulant, thrombolytic), risk factors (cocaine, amphetamine, smoking, alcohol abuse), and details and diagnostic and etiological workup (brain magnetic resonance imaging, angiogram and complete laboratory workup including coagulation panels from baseline, complete autopsy report), the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral haemorrhage	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04182614 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220104 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A441404()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210514 CCYYMMDD	20211121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A441404

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	E2B_04182614 [redacted] CA-AstraZeneca-2021A441404

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Thrombocytopenia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown-10 doses of 0.5ml		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombocytopenia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombocytopenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a patient of unknown gender (age not provided) of Unknown ethnic origin.

No medical history and no concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number), dose unknown via intramuscular route, for product used for unknown indication on an unknown date. On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia).

Action taken with suspect product Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable. Officials reported that person was being treated in hospital. The patient died from the event on an unspecified date. It was not known whether an autopsy was performed. The cause of death was thrombocytopenia.

The event thrombocytopenia was considered serious due to seriousness criteria of death and important medical event.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Summary of insignificant follow-up information received by AstraZeneca received on 25-MAY-2021:A spontaneous report has received via consumer. New information included the addition of another consumer.

Summary of follow up information received by Astrazeneca on 21-NOV-2021. A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer. Significant information included the Regulatory authority reporter type was added. Suspect product indication was added. Event verbatim updated. Narrative added and updated. Corrected report 24-NOV-2021: Action taken was changed to not applicable.

Corrected report on 04-Jan-2022: The case was suppressed as No patient identifier were available (Non-Valid).CAUSE OF DEATH: THROMBOCYTOPENIA NULLIFICATION/AMENDMENT REASON: Amendment: Non-Valid
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of Thrombocytopenia is not listed in the company core data sheet of AZD1222. The cause of death was thrombocytopenia. Due to limited information on the relevant medical history, concurrent diseases, concomitant medication, autopsy details, pre-disposing risk factors (smoking, alcohol use, immune-related conditions), exposure to specific factors, detailed diagnostic (computerized tomography scan, pulmonary angiography, complete blood count, Bone marrow scan, prothrombin time, partial thromboplastin time , venous ultrasound, contrast venography, and blood test, D-dimer test, ophthalmological work up) and etiologic workup, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

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Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
PRIVACY

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
PRIVACY	ON

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)		
Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04216152 (3)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211201 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-050842(4)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210520 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211125 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-050842

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) HEALTHCANVIG HEALTHCANVIG 01001927719	**Duplicate Case identifiers (A.1.11.2)** CA-HEALTHCANVIG-000946849 CA-HEALTHCANVIG-E2B_04149686 CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-050842

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_04149686, (1) E2B_04674509

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - BRISTOL-MYERS SQUIBB

Patient (B.1)

Patient Initial (B.1.1) [redacted]	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 91 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04216152 (3)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Chills
26.0	Craniocerebral injury
26.0	Fall
26.0	Hemorrhagic stroke
26.0	Pyrexia
26.0	Subarachnoid haemorrhage
26.0	Subdural haemorrhage
26.0	Vomiting

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ELIQUIS FILM COATED	
Active Substance names (B.4.k.2.2) apixaban		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 5 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6) 5 milligram, bid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Oral	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Cerebrovascular accident prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	

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Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chills	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chills	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Craniocerebral injury	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Craniocerebral injury	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pyrexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Pyrexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	No Information

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	BNT162B2	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ATENOLOL	
Active Substance names (B.4.k.2.2)		
atenolol		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02255634 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
50 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
50 milligram, qd		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
TABLET	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Atrial fibrillation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

STROKE; CEREBRAL BLEEDING/HEMORRHAGIC CVA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hemorrhagic stroke		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Haemorrhagic stroke		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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CRANIOCEREBRAL INJURY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Craniocerebral injury		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Craniocerebral injury		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fall		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fall		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUBARACHNOID HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Subarachnoid haemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Subarachnoid haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUBDURAL HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Subdural haemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Subdural haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHILLS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Chills		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Chills		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PYREXIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pyrexia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pyrexia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VOMITING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vomiting
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vomiting

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

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Summary (B.5)

Case narrative (B.5.1)

This case was initially received via Pfizer Inc (Reference number: 2021498435) on 20-May-2021. The most recent information was received on 25-Nov-2021 and was forwarded to BMS on 25-Nov-2021.
This spontaneous case was reported by a physician and describes the occurrence of fatal HAEMORRHAGIC STROKE (Stroke; Cerebral bleeding/Hemorrhagic CVA), fatal CRANIOCEREBRAL INJURY, fatal FALL, fatal SUBARACHNOID HAEMORRHAGE, fatal SUBDURAL HAEMORRHAGE, fatal CHILLS, fatal PYREXIA and fatal VOMITING in 91-year-old female patient who received apixaban (Eliquis) film-coated tablet for Cerebrovascular accident prophylaxis.

CO-SUSPECT PRODUCTS included Bnt162b2 for COVID-19 immunization and Atenolol tablet for Atrial fibrillation.

The patient's past medical history included CVA on 26-Apr-2017, TIA (Recurrent TIA in 2011) in 2011 and Coronary artery disease in 2013.
Concurrent medical conditions included AFib.

On an unknown date, the patient started Eliquis (Oral), 5 milligram twice a day, Bnt162b2 (unknown route) at an unspecified dose Total and Atenolol (Oral), 50 milligram once a day. On an unknown date, the patient experienced HAEMORRHAGIC STROKE (seriousness criteria death, hospitalization and medically significant), CRANIOCEREBRAL INJURY (seriousness criteria death and medically significant), FALL (seriousness criteria death and medically significant), SUBARACHNOID HAEMORRHAGE (seriousness criteria death and medically significant), SUBDURAL HAEMORRHAGE (seriousness criteria death and medically significant), CHILLS (seriousness criteria death, hospitalization and medically significant), PYREXIA (seriousness criteria death, hospitalization and medically significant) and VOMITING (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized on 25-Apr-2021 due to Haemorrhagic stroke. The action taken with Eliquis(Oral) was unknown. The patient died on 25-Apr-2021. The reported cause of death was hemorrhagic cva, Craniocerebral injury, Fall, Subarachnoid haemorrhage, Subdural haemorrhage, Chills, Pyrexia and Vomiting. It is unknown if an autopsy was performed. Apixaban was used for Afib. The patient received co-suspect drug BNT162B2 vial contains 6 doses of 0.3 ml after dilution in intramuscular suspension at a frequency of total with therapy duration of 1 day. The patient received atenolol in tablet dosage form.

Patient was admitted and treated in the hospital. Patient was admitted to hospital on [redacted]2021 and died of hemorrhagic CVA.

Action taken with suspect therapies in response to events were not reported.

For Eliquis(Oral), the reporter did not provide any causality assessments.
Case received from Canada health authority: CA-HEALTHCANVIG-000946849
Correction to this file was done on 28-May-2021, based on the information previously received on 20-MAY-2021 following change was made: BNT162B2 was coded as co-suspect product in the product tab (previously coded as Covid-19 Vaccine).

Most recent follow-up information received from consumer via Canada HA on 05-Jul-2021 incorporated above includes: Added new events.

Most recent follow-up information received from the other health professional via Canada Health Authority (CA-HEALTHCANVIG-E2B_04149686) incorporated above includes: 07-SEP-2021 Suspect product, product attributes and New events added. Atenolol was considered as additional suspect. Events Chills, Pyrexia and Vomiting were added additionally.

Most recent follow-up information received from other health professional via Canada HA on 25-Nov-2021 incorporated above includes: suspect product details, event attributes and narrative updated.

Further company follow-up with the Physician is not possible.

BMS medical evaluation comment:
This 91-year-old patient died due to fall, craniocerebral injury, subarachnoid haemorrhage, subdural haemorrhage, hemorrhagic stroke, pyrexia, chills and vomiting after receiving apixaban therapy. Based on the elderly age and nature of the reported events fall leading to craniocerebral injury is considered not related to suspect therapy. Although fall contributed, considering the anticoagulant nature of suspect therapy, its causal role in the reported fatal bleeding events hemorrhagic stroke, subdural hemorrhage and subarachnoid hemorrhage is considered possible. Pyrexia, chills and vomiting are likely manifestations secondary to fatal bleeding events.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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BMS medical evaluation comment:
This 91-year-old patient died due to fall, craniocerebral injury, subarachnoid haemorrhage, subdural haemorrhage, hemorrhagic stroke, pyrexia, chills and vomiting after receiving apixaban therapy. Based on the elderly age and nature of the reported events fall leading to craniocerebral injury is considered not related to suspect therapy. Although fall contributed, considering the anticoagulant nature of suspect therapy, its causal role in the reported fatal bleeding events hemorrhagic stroke, subdural hemorrhage and subarachnoid hemorrhage is considered possible. Pyrexia, chills and vomiting are likely manifestations secondary to fatal bleeding events.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	CVA	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
20170426 CCYYMMDD		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	AFib	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	TIA	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2011 CCYY		
Comments (B.1.7.1g)		
Recurrent TIA in 2011		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Coronary artery disease	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2013 CCYY		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemorrhagic stroke	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Craniocerebral injury	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fall	

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Subarachnoid haemorrhage	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Subdural haemorrhage	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chills	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pyrexia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Vomiting	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04220040 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210528 CCYYMMDD
	HC Initial Received Date:	20210528 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A402780()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210505 CCYYMMDD	20210518 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A402780

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
MC CANADA AZPROD0000	[redacted] CA-AstraZeneca-2021A402780

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
	Adult		
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Low platelets
26.0	Thrombocytopenia
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VACCINE-INDUCED THROMBOTIC THROMBOCYTOPENIA/LOW PLATELETS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VACCINE-INDUCED THROMBOTIC THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer. The report concerns an adult of unknown gender of Unknown ethnic origin.

No medical history was reported.

No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN) 0.5 ml, via intramuscular route, on an unknown date.

On an unknown date, the patient experienced vaccine-induced thrombotic thrombocytopenia/low platelets (preferred term: Thrombocytopenia). On an unknown date, the patient experienced vaccine-induced thrombotic thrombocytopenia (preferred term: Thrombosis).

It is unknown if any action was taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)).

The patient died from the event of vaccine-induced thrombotic thrombocytopenia/low platelets and vaccine-induced thrombotic thrombocytopenia on an unspecified date.

It is not known whether an autopsy was performed. The cause of death was low platelets, vaccine-induced thrombotic thrombocytopenia and vaccine-induced thrombotic thrombocytopenia.

The events were considered serious (death, hospitalised and important medical event).

Follow-up of insignificant information received by AstraZeneca on 18-MAY-2021 via consumer.Two new reporters were added and Narrative was updated .CAUSE OF DEATH: LOW PLATELETS CAUSE OF DEATH: VACCINE-INDUCED THROMBOTIC THROMBOCYTOPENIA CAUSE OF DEATH: VACCINE-INDUCED THROMBOTIC THROMBOCYTOPENIA
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal Thrombocytopenia and Thrombosis are not listed in the company core data sheet of AZD1222. Due to limited information on age, gender, health status and blood counts at baseline, circumstances leading to the events, date for vaccination, onset date, relevant medical history including habits such as smoking and alcohol consumption, concomitant medication, etiologic and diagnostic work up and autopsy report, If performed, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Low platelets	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

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Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04223862 (2)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211124 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A472858()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210525 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211121 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A472858

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) HEALTH CANADA MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B 04223862 [redacted] CA-AstraZeneca-2021A472858

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 60 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Chronic thrombocytopenia
26.0	Clot blood
26.0	Thrombocytopenia
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2) chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose 1-1st dose		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Product used for unknown indication
Start date of drug (B.4.k.12) 202[redacted] CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEVELOPED BLOOD CLOT SYMPTOMS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH CAUSED BY VACCINE INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT)

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis with thrombocytopenia syndrome		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis with thrombocytopenia syndrome		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report had been received from the regulatory authority in Canada (HEALTH CANADA) via consumer. The report concerned a patient of unknown gender of Unknown ethnic origin of age 6 decades.

No medical history and no concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for product used for unknown indication on [redacted]2021. Seventeen days later, the patient experienced developed blood clot symptoms (preferred term: Thrombosis). On an unknown date, the patient experienced death caused by vaccine induced immune thrombotic thrombocytopenia (vitt) (preferred term: Thrombocytopenia). On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia). On an unknown date, the patient experienced thrombosis (preferred term: Thrombosis). The patient went to hospital 17 days later after receiving vaccine. They were previously reported as hospitalized.

The action taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable. Treatment included hospitalization of patient. The patient died from the events of death caused by vaccine induced immune thrombotic thrombocytopenia (vitt), developed blood clot symptoms, thrombocytopenia and thrombosis on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was developed blood clot symptoms, death caused by vaccine-induced immune thrombotic thrombocytopenia (vitt), thrombocytopenia and thrombosis.

The events death caused by vaccine induced immune thrombotic thrombocytopenia (vitt), developed blood clot symptoms, thrombocytopenia and thrombosis were considered serious due to death. The events death caused by vaccine induced immune thrombotic thrombocytopenia (vitt), developed blood clot symptoms, thrombocytopenia and thrombosis were considered serious due to hospitalised. The events death caused by vaccine induced immune thrombotic thrombocytopenia (vitt), thrombocytopenia and thrombosis were considered serious due to important medical event.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow up information received by AstraZeneca on 11-OCT-2021 from the health authority via consumer. New reporter of regulatory authority and regulatory identification number were added. New events of thrombocytopenia and thrombosis were added. Death tab was updated. Narrative was updated. Minor correction 25-OCT-2021: Seriousness criteria of important medical event for the event developed blood clot symptoms was deleted and suspect indication was added. Associated case ID added.

Summary of follow-up information received by AstraZeneca on 21-NOV-2021. The following information was updated. Meddra version was updated for Thrombocytopenia and Thrombosis. Dosage form was updated. As per the MA comment the event of THROMBOCYTOPENIA was coded to LLT: Thrombocytopenia and DEATH CAUSED BY VACCINE INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT) was coded to LLT: Thrombosis with thrombocytopenia syndrome. Minor correction 23-NOV-2021: Last name of RA was corrected, Disease continues was changed to unknown for Product used for unknown indication, age at onset was added, narrative was corrected.
CAUSE OF DEATH: DEVELOPED BLOOD CLOT SYMPTOMS CAUSE OF DEATH: DEATH CAUSED BY VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT) CAUSE OF DEATH: THROMBOCYTOPENIA CAUSE OF DEATH: THROMBOSIS
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Thrombosis with thrombocytopenia syndrome is listed in company core data sheet of AZD1222. However, since the event was reported with a fatal outcome, it is considered unlisted. Due to limited information regarding relevant medical history (deep venous thrombosis, traumatic injury, neoplastic disease, thrombophilia, aplastic anemia, cirrhosis, leukemia, myelodysplasia, autoimmune disorder), family history of venous thromboembolism, concurrent conditions (such as chronic obstructive pulmonary disease, congestive heart failure, infections), clinical course, etiological and diagnostic work up (complete physical examination, complete blood count with D dimer test and infectious profile, electrocardiogram, chest x-ray, ultrasonography, echocardiography, other relevant imaging studies), treatment details, further clarification of the event, concomitant medication, risk factors (prolonged immobilization, smoking), and complete autopsy report, the evaluation did not find evidence to suggest aa causal relationship between the event and AZD 1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Clot blood	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Thrombocytopenia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Chronic thrombocytopenia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Thrombosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	**DOB of Parent** (B.1.10.2.1)	**Age** (B.1.10.2.2)	**LMP date** (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	**Medical history** (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) PRIVACY	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) HEALTH CANADA
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) Confidential
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Tropiano, Stephano (HC/SC)

From: Saliba, Lee (HC/SC)
Sent: 2021-04-09 10:11 AM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Cc: Canada Vigilance (HC/SC); Litowitz, Paul (HC/SC)
Subject: FW: PUB-001093 FW:

Categories: COVID

Hello,
Could you please enter the report below and notify me when the AER is created?

Merci / Thank you,
Lee

From: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Sent: 2021-04-07 3:09 PM
To: Saliba, Lee (HC/SC) <lee.saliba@canada.ca>
Subject: PUB-001093 FW:

Hi Lee,

Can I assign this French inquiry to you? I haven't sent this report to EFAX yet, but I think we should?

Thanks,
Chris

\\Ncr-a-irbv1s\IRBV1\HC\HPFB\MHPD\MHPSEIB-PROS\COMMUNICATIONS GC2\ENQUIRIES\Correspondence\Public\2021\PUB-001093_Carole Isabelle

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From: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Sent: 2021-04-07 2:50 PM
To: [redacted]
Cc: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Subject: RE:

Bonjour,

Nous vous remercions d'avoir communiqué avec Santé Canada.

Votre demande a été réacheminée au bureau approprié pour fin de réponse.

Veuillez agréer, Madame, Monsieur, l'expression de nos sentiments les meilleurs.

Santé Canada | Health Canada
Ottawa, Canada K1A 0K9
info@hc-sc.gc.ca
Téléphone | Telephone 613-957-2991 / Sans frais | Toll free 1 866-225-0709 /

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Télécopieur | Facsimile 613-941-5366 / Téléimprimeur | Teletypewriter 1 800-267-1245
Gouvernement du Canada | Government of Canada

From: [redacted]
Sent: 2021-04-05 3:59 PM
To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Subject:

Bonjour,

J aimerais rapporter le décès de mon père vaccinés avec Moderna et mort d une infection pulmonaire sévère.

J aimerais être sûre que ces effets secondaires soit comptabilisé dans les renseignement sur les vaccins.

[redacted]

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: Canada Vigilance (HC/SC)
Sent: 2021-04-13 3:09 PM
To: [redacted]
Subject: Correspondence from Marketed Health Products Directorate

Follow Up Flag: Follow up
Flag Status: Completed

Chère [redacted]

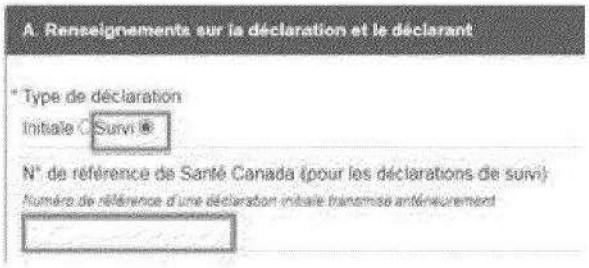
Nous vous remercions d'avoir communiqué des renseignements sur des effets indésirables à Santé Canada, le 5 Avril 2021, concernant le produit de santé Vaccin Moderna. Nous désirons vous présenter nos plus profondes sympathies pour votre perte et comprenons que ceci doit être une situation difficile pour vous. Nous sommes reconnaissants du temps que vous avez pris pour nous faire part de cette tragédie et espérons que nous saurons répondre à vos préoccupations.

Le Programme Canada Vigilance est le programme de surveillance après la mise en marché de Santé Canada qui recueille et évalue les déclarations d'effets indésirables soupçonnés associés aux produits de santé qui ont été soumises par des détenteurs d'une autorisation de mise en marché (c.-à-d. des fabricants) et des hôpitaux ou par des professionnels de la santé et des consommateurs, soit directement à Santé Canada, soit par l'entremise des fabricants ou des hôpitaux.

L'information que vous avez fournie dans votre déclaration a été enregistrée dans la base de données du Programme Canada Vigilance sous le numéro d'effet indésirable **945271**. En raison de ces activités de surveillance, Santé Canada souhaite obtenir des renseignements supplémentaires au sujet de cet incident, particulièrement les renseignements suivants s'ils vous sont disponibles et/ou accessibles :

- Le numéro de lot du vaccin
- La date que le produit a été administré
- Les dates en lien avec les effets secondaires
- L'âge de votre père
- Les antécédents médicaux de votre père
- Les médicaments pris par votre père
- Les résultats de laboratoires et/ou investigations en lien avec l'infection pulmonaire
- Les traitements reçus

Nous vous invitons donc à fournir les renseignements supplémentaires mentionnés ci-haut en utilisant l'application de déclaration en ligne disponible pour déclarer un effet secondaire. S'il vous plaît, assurez-vous de sélectionner « suivi » sous *Type de déclaration* et d'indiquer votre numéro d'effet indésirable (**945271**) sous le *Numéro de référence de Santé Canada* :



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Toute personne qui est témoin d'une réaction possible à un vaccin ou qui a une telle réaction est invitée à la signaler à son fournisseur de soins de santé. Les fournisseurs de soins de santé déclarent les effets secondaires possibles suivant l'immunisation au bureau local de santé publique qui, à son tour, les signale à l'Agence de la santé publique du Canada par l'intermédiaire des autorités fédérales, provinciales ou territoriales en matière d'immunisation.

Pour votre information, la déclaration en ligne au Programme Canada Vigilance de Santé Canada concernant les effets secondaires des vaccins a été mise à jour. Les révisions clarifient les procédures établies et facilitent la déclaration des effets secondaires des vaccins, y compris ceux contre la COVID-19.

D'autres renseignements concernant les lignes directrices sur la déclaration des effets secondaires des vaccins pour les consommateurs sont disponibles à la page Web Déclarer un effet secondaire à un vaccin : déclarant en sélectionnant « Consommateur » comme déclarant.

Si vous désirez être tenue au courant des communications de Santé Canada au sujet des avis, retraits et autres communications sur les produits de santé, vous pouvez vous inscrire à MedEffet.

Une fois de plus, nous aimerions vous exprimer nos sincères condoléances et vous souhaitons le meilleur. N'hésitez pas à contacter le Programme Canada Vigilance si vous nécessitez de plus amples informations.

Sincèrement,

Canada Vigilance Program
Health Canada, Government of Canada
hc.canada.vigilance.sc@canada.ca / Tel: 1-866-234-2345/ TTY: 1-800-465-7735

Programme Canada Vigilance
Santé Canada, Gouvernement du Canada
hc.canada.vigilance.sc@canada.ca/ Tél. : 1-866-234-2345/ ATS : 1-800-465-7735

Health Canada Santé Canada

From: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Sent: 2021-04-07 2:50 PM
To [redacted]
Cc: Canada Vigilance (HC/SC) <hc.canada.vigilance.sc@canada.ca>
Subject: RE:

Bonjour,

Nous vous remercions d'avoir communiqué avec Santé Canada.

Votre demande a été réacheminée au bureau approprié pour fin de réponse.

Veuillez agréer, Madame, Monsieur, l'expression de nos sentiments les meilleurs.

Santé Canada | Health Canada
Ottawa, Canada K1A 0K9
info@hc-sc.gc.ca

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A2023000085

ATIA - 19(1)

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Téléphone | Telephone 613-957-2991 / Sans frais | Toll free 1 866-225-0709 /
Télécopieur | Facsimile 613-941-5366 / Téléimprimeur | Teletypewriter 1 800-267-1245
Gouvernement du Canada | Government of Canada

From: [redacted]
Sent: 2021-04-05 3:59 PM
To: Info SC, HC Info (HC/SC) <hcinfo.infosc@canada.ca>
Subject:

Bonjour,

J aimerais rapporter le décès de mon père vaccinés avec Moderna et mort d une infection pulmonaire sévère.

J aimerais être sûre que ces effets secondaires soit comptabilisé dans les renseignement sur les vaccins.

[redacted]

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A2023000085

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04230137 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211018 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A476550()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210526 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211011 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A476550

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC CANADA MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_04230137 [redacted] CA-AstraZeneca-2021A476550

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 50 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04230137 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Thrombocytopenia
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 1		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a male patient of Unknown ethnic origin (age 5 decades).

No medical history and no concomitant products were reported.

The patient received dose 1 Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadoxl ncov-19)), via intramuscular route, on an unknown date.
On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia). On an unknown date, the patient experienced thrombosis (preferred term: Thrombosis). Patient reported its first death linked to a rare blood clot associated with the Oxford-AstraZeneca vaccine as many who received a first dose of the vaccine faced challenges trying to schedule second shots. The reporter said that there had been 13 cases of VITT in the province so far. The patient death was the fifth fatal case of VITT in an AstraZeneca recipient in Canada. Experts maintain the syndrome was exceedingly rare and treatable in most cases. The government had reported the first fatal case of an extremely rare blood clot that had been detected in a small number of residents who received the AstraZeneca/COVISHEILD COVID-19 Vaccine. It was one of 41 deaths linked to COVID-19. The health professional said that, a man in his 40s who received a first dose of the AstraZeneca vaccine at the end of April passed away a few weeks later. The death was still being investigated and it was said that the man had vaccine induced immune thrombotic thrombocytopenia, also known as VITT. While the investigation was ongoing and a final cause of death had yet to be officially determined, it had been confirmed the first death of a person with a rare blood clot who received a dose of the AstraZeneca COVID-19 vaccine in April was associated with VITT (vaccine induced immune thrombotic thrombocytopenia). The risks associated with this vaccine are rare, but they are real, she added. Reporter had total of 16 cases of thrombotic thrombocytopenia, of which 13 cases now meet the criteria for VITT. No other details regarding the deceased person had been released.

The action taken for Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable with respect to all the events. The patient died from the event of thrombocytopenia and thrombosis on an unspecified date.

The cause of death was thrombocytopenia and thrombosis. It was not known whether an autopsy was performed.

The events of thrombocytopenia and thrombosis were considered as serious due to seriousness criteria death and important medical event .

Summary of follow-up information received by AstraZeneca on 11-Oct-2021.A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer,the reporter regulatory authority was added. The event verbatims was updated from vaccine-induced thrombotic thrombocytopenia (VITT) to thrombocytopenia and thrombotic to thrombosis. New reference added. Minor correction 14-Oct-2021: Age group Adult was removed and age at onset 5 decades added.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.CAUSE OF DEATH: THROMBOCYTOPENIA CAUSE OF DEATH: THROMBOSIS
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Thrombosis(reported as Thrombosis) in combination with Thrombocytopenia(reported as Thrombocytopenia) is listed in the company core data sheet of AZD 1222. However since the events were reported with a fatal outcome it is considered unlisted. The cause of death was Thrombocytopenia and Thrombosis. However due to limited information on further clarification of the event, details and circumstances surrounding the event, baseline health condition before vaccination, medical history, specific risk factors (coagulation disorders, malnutrition, dehydration, electrolyte imbalance, infections), autopsy details, etiologic and diagnostic workup (complete blood panel including infection profile, coagulation profile, electrocardiogram, echocardiogram, serum electrolytes, coagulation profile, relevant imaging studies), the evaluation did not find evidence to suggest a causal relationship between the events and vaccine.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

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Canada Vigilance AER#:	E2B_04230137 (1)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04248624 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211201 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A492961()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210531 CCYYMMDD	20211121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A492961

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	E2B 04248624 [redacted] CA-AstraZeneca-2021A492961

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (2) , (2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			61 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04248624 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Afebrile seizure
26.0	Apnea
26.0	Appetite lost
26.0	Cerebellar ataxia
26.0	Cerebellar disorder NOS
26.0	Cerebral hemorrhage
26.0	Cerebral venous thrombosis
26.0	Circulatory collapse
26.0	Fibrin D dimer increased
26.0	Fibrinogen
26.0	Flu-like symptoms
26.0	Heparin-platelet factor 4 antibody complex test positive
26.0	Lethargic
26.0	Loss of consciousness
26.0	Nausea
26.0	Neurological symptoms NOS
26.0	Numbness
26.0	Paresthesia
26.0	Persistent headache
26.0	Personality change
26.0	Platelet count low
26.0	Pulmonary thrombosis
26.0	Strength loss of
26.0	Thrombocytopenia
26.0	Tremor
MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

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26.0	Unable to walk
MedDRA version for cause (B.1.9.2.a)	**Reported cause(s)** (B.1.9.2.b)
26.0	Unresponsive to stimuli
MedDRA version for cause (B.1.9.2.a)	**Reported cause(s)** (B.1.9.2.b)
26.0	Weakness left or right side

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2) chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)** 4120Z029	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose 1		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Product used for unknown indication
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) **Current reaction**

THROMBOCYTOPENIA

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Thrombocytopenia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Thrombocytopenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNABLE TO AMBULATE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unable to walk
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Gait inability

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
2 Weeks		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WEAKNESS LEFT OR RIGHT SIDE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Weakness left or right side
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Hemiparesis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
2 Weeks		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNRESPONSIVE TO STIMULI

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unresponsive to stimuli
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Unresponsive to stimuli

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PARESTHESIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Paraesthesia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Paraesthesia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NUMBNESS AND TINGLING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Numbness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Hypoaesthesia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PULMONARY THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Pulmonary thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL VENOUS THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral venous thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cerebral venous thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

AFEBRILE SEIZURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Afebrile seizure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Seizure		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
7 Days		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COLLAPSED AND BECAME APNEIC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Circulatory collapse
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Circulatory collapse

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PLT: 25

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Platelet count low
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Platelet count decreased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

APPETITE LOST

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Appetite lost
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Decreased appetite

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Nausea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nausea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FLU LIKE SYMPTOMS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Flu-like symptoms
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Influenza like illness

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PERSISTENT HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Persistent headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBELLAR ATAXIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebellar ataxia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Cerebellar ataxia		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
2 Weeks		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LETHARGIC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lethargic		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Lethargy		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

TREMOR

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Tremor		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Tremor		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
7 Days		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUDDEN LOSS OF CONSCIOUSNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Loss of consciousness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Loss of consciousness		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
7 Days		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

PERSONALITY CHANGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Personality change
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Personality change

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FOCAL OR MULTIFOCAL NEUROLOGICAL SIGNS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Neurological symptoms NOS
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Neurological symptom

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW STRENGTH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Strength loss of
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Asthenia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
2 Weeks		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBELLAR SYMPTOMS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cerebellar disorder NOS
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nervous system disorder

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
2 Weeks		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MASSIVE LEFT HEMISPHERIC INTRAPARENCHYMAL HEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cerebral hemorrhage
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebral haemorrhage

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

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No

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

APNEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Apnea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Apnoea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

D-DIMER: 21470

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Fibrin D dimer increased
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Fibrin D dimer increased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FIBRINOGEN: 2.54

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Fibrinogen
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Blood fibrinogen

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ANTI PF4 ELISA AND SRA POSITIVE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heparin-platelet factor 4 antibody complex test positive
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Heparin-induced thrombocytopenia test positive

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a 61 years old male patient of Unknown ethnic origin.

The patients past and current medical history included skin cancer (metastatic malignant melanoma) excision and no concomitant products were reported.

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ATIA - 19(1)

The patient received Dose 1 of Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number 4120Z029), via intramuscular route, for product used for unknown indication on [redacted]2021.

On an unknown date, 2 weeks after starting treatment with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml, the patient experienced unable to ambulate (preferred term: Gait inability), weakness left or right side (preferred term: Hemiparesis), cerebellar ataxia (preferred term: Cerebellar ataxia), low strength (preferred term: Asthenia) and cerebellar symptoms (preferred term: Nervous system disorder). On an unknown date, 1 week after starting treatment with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml, the patient experienced afebrile seizure (preferred term: Seizure), tremor (preferred term: Tremor) and sudden loss of consciousness (preferred term: Loss of consciousness). On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia), unresponsive to stimuli (preferred term: Unresponsive to stimuli), paresthesia (preferred term: Paraesthesia), numbness and tingling (preferred term: Hypoaesthesia), pulmonary thrombosis (preferred term: Pulmonary thrombosis), cerebral venous thrombosis (preferred term: Cerebral venous thrombosis), collapsed and became apneic (preferred term: Circulatory collapse), plt: 25 (preferred term: Platelet count decreased), appetite lost (preferred term: Decreased appetite), nausea (preferred term: Nausea), flu like symptoms (preferred term: Influenza like illness), persistent headache (preferred term: Headache), lethargic (preferred term: Lethargy), personality change (preferred term: Personality change), focal or multifocal neurological signs (preferred term: Neurological symptom), massive left hemispheric intraparenchymal hemorrhage (preferred term: Cerebral haemorrhage), apnea (preferred term: Apnoea), d-dimer: 21470 (preferred term: Fibrin D dimer increased), fibrinogen: 2.54 (preferred term: Blood fibrinogen) and anti pf4 elisa and sra positive (preferred term: Heparin-induced thrombocytopenia test positive). As per reporter 61 years male patient with history of right chest skin cancer removed a month before the Covid vaccine. 7 days after the vaccine developed seizure, witnessed by the health care provider, sudden loss of consciousness and tremor. He had lethargy and personality change for greater or equal to 24 hrs had focal or multifocal neurological signs along with numbness and tingling. 2 weeks after the vaccine, patient was admitted to the emergency room: very ataxic, unable to ambulate, low strength, cerebellar symptoms and patient had right sided weakness. On the following day patient experienced collapsed and became apneic, was intubated and stabilized. On an unknown date, platelet count was measured and it was found to be 25 (units not specified), D-dimer was measured and result was 21470 (units not specified), fibrinogen was measured and it was found to be 2.54 (units not specified), magnetic resonance imaging (MRI) venogram was performed and result was massive left hemispheric intraparenchymal hemorrhage, CT PE PROTOCOL was performed and result was Pulmonary embolism (PE) in left lower lobe, Anti PF4 was found to be positive, ELISA was performed and it was found to be positive and Serotonin release assay was performed and it was found to be positive.

Action taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable.

The patient died from the event of thrombocytopenia, unable to ambulate, weakness left or right side, unresponsive to stimuli, paresthesia, numbness and tingling, pulmonary thrombosis, cerebral venous thrombosis, afebrile seizure, collapsed and became apneic, plt: 25, appetite lost, nausea, flu like symptoms, persistent headache, cerebellar ataxia, lethargic, tremor, sudden loss of consciousness, personality change, focal or multifocal neurological signs, low strength, cerebellar symptoms, massive left hemispheric intraparenchymal hemorrhage, apnea, d-dimer: 21470, fibrinogen: 2.54 and anti pf4 elisa and sra positive on [redacted]2021.

It was not known whether an autopsy was performed. The cause of death was thrombocytopenia, unable to ambulate, weakness left or right side, unresponsive to stimuli, paresthesia, numbness and tingling, pulmonary thrombosis, cerebral venous thrombosis, afebrile seizure, collapsed and became apneic, plt: 25, appetite lost, nausea, flu-like symptoms, persistent headache, cerebellar ataxia, lethargic, tremor, sudden loss of consciousness, personality change, focal or multifocal neurological signs, low strength, cerebellar symptoms, massive left hemispheric intraparenchymal hemorrhage, apnea, d-dimer: 21470, fibrinogen: 2.54 and anti pf4 elisa and sra positive.

The events were considered serious (death, hospitalised and important medical event).

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 vaccine is an Astrazeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca/MedImmune 11-OCT-2021 A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer: Regulatory authority as a reporter was added. Suspect product indication was added, event verbatim for event became apneic and apnea was changed to apnea and verbatim for collapsed was changed to collapsed and became apneic. Lowest level term of event d-dimer: 21470 was changed from D-dimer high to D-dimer, anti pf4 elisa and sra positive was changed from ELISA to Heparin-induced thrombocytopenia test positive as per company physician. Laboratory data was updated. Corrected Report 19-OCT-2021: Action taken was changed to not applicable.

Minor correction 21-Oct-2021: correction to company clinical comment.

Summary of follow-up information received by AstraZeneca on 21-NOV-2021. A spontaneous report was received from the regulatory authority via consumer: The Seriousness criteria as important medical event (IME) was added for all the events and narrative updated accordingly.
CAUSE OF DEATH: THROMBOCYTOPENIA CAUSE OF DEATH: UNABLE TO AMBULATE CAUSE OF DEATH: WEAKNESS LEFT OR RIGHT SIDE CAUSE OF DEATH: UNRESPONSIVE TO STIMULI CAUSE OF DEATH: PARESTHESIA CAUSE OF DEATH: NUMBNESS AND TINGLING CAUSE OF DEATH: PULMONARY THROMBOSIS CAUSE OF DEATH: CEREBRAL VENOUS THROMBOSIS CAUSE OF DEATH: AFEBRILE SEIZURE CAUSE OF DEATH: COLLAPSED AND BECAME APNEIC CAUSE OF DEATH: PLT: 25 CAUSE OF DEATH: APPETITE LOST CAUSE OF DEATH: NAUSEA CAUSE OF DEATH: FLU-LIKE SYMPTOMS CAUSE OF DEATH: PERSISTENT HEADACHE CAUSE OF DEATH: CEREBELLAR ATAXIA CAUSE OF DEATH: LETHARGIC CAUSE OF DEATH: TREMOR CAUSE OF DEATH: SUDDEN LOSS OF CONSCIOUSNESS CAUSE OF DEATH: PERSONALITY CHANGE CAUSE OF DEATH: FOCAL OR MULTIFOCAL NEUROLOGICAL SIGNS CAUSE OF DEATH: LOW STRENGTH CAUSE OF DEATH: CEREBELLAR SYMPTOMS CAUSE OF DEATH: MASSIVE LEFT HEMISPHERIC INTRAPARENCHYMAL HEMORRHAGE CAUSE OF DEATH: APNEA CAUSE OF DEATH: D-DIMER: 21470 CAUSE OF DEATH: FIBRINOGEN: 2.54 CAUSE OF DEATH: ANTI PF4 ELISA AND SRA POSITIVE
Lab Test #1 : 10035525 Lab Test #2 : 10016577 Lab Test #3 : 10016595 Unstructured Test Result (Test #4) : massive left hemispheric intraparenchymal hemorrhage Lab Test #4 : 10028049 Lab Test #5 : 10078646 Lab Test #6 : 10060192 Lab Test #7 : 10059717 Lab Test #8 : 10085478 Lab Test #9 : 10035525
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Thrombosis (Preferred term: Hemiparesis & Preferred term: Pulmonary thrombosis & Preferred term :Cerebral venous thrombosis) in combination with thrombocytopenia (Preferred term: Thrombocytopenia & Preferred term: Platelet count decreased) , Headache, Decreased appetite, Lethargy, Tremor, Asthenia, Nausea and Influenza like illness are listed in the company core data sheet of AZD1222. However, since the events were reported with a fatal outcome it is considered unlisted. Fatal events of Gait inability, Unresponsive to stimuli, Paraesthesia, Hypoaesthesia, Seizure, Circulatory collapse, Cerebellar ataxia, Loss of consciousness, Personality change, Neurological symptom, Nervous system disorder, Cerebral haemorrhage , Apnoea, Fibrin D dimer increased & Heparin-induced thrombocytopenia test positive are not listed in company core data sheet of AZD1222. Additionally, Blood fibrinogen was also reported with this case. The events could be in association with each other. Underlying, medicaal history of skin cancer(metastatic malignant melanoma) could be contributory risk factors to the events of Thrombosis. Due to limited information on baseline health condition before vaccination, relevant family history, concurrent diseases (infections), concomitant medications (heparin), all events onset dates, details and circumstances surrounding the events, genetic conditions predisposing to thrombosis (factor V Leiden, protein C or S deficiency), other possible risk factors(smoking, obesity, prolonged bed rest), lifestyle (alcohol), autopsy report and detailed diagnostic and etiologic workup (clinical assessment, hematologic evaluation, medical notes from a health care provider), the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	CT pulmonary angiogram	Pulmonary embolism (PE) in left lower lobe	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	ELISA		
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Fibrin D dimer	21470	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Fibrinogen	2.54	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	MRI	massive left hemispheric intraparenchymal hemor...	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Platelet count	25 (units not specified)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Platelet count	low	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Platelet factor 4		
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Serotonin release assay		
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

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Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Skin cancer metastatic	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
20210305 CCYYMMDD	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unable to walk	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Weakness left or right side	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unresponsive to stimuli	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Paresthesia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Numbness	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pulmonary thrombosis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral venous thrombosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Afebrile seizure	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Circulatory collapse	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Platelet count low	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Appetite lost	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Nausea	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Flu-like symptoms	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Persistent headache	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebellar ataxia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

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Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Lethargic	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Tremor	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Loss of consciousness	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Personality change	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Neurological symptoms NOS	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Strength loss of	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Cerebellar disorder NOS	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Cerebral hemorrhage	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Apnea	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fibrin D dimer increased	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fibrinogen	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heparin-platelet factor 4 antibody complex test positive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		**Drug end date** (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		**Indication** (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		**Reactions** (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) PRIVACY	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) CANADIAN HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) PRIVACY	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4)	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) PRIVACY	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) UNKNOWN
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4)	
Literature reference(s) (A.2.2)			

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Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	
Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) Confidential
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04251222 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211013 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A495054()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210601 CCYYMMDD	20211011 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A495054

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA MC CANADA AZPROD0000	E2B 04251222 [redacted] CA-AstraZeneca-2021A495054

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04251222 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RARE BLOOD CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a patient.

No medical history and no concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, on an unknown date. On an unknown date, the patient experienced rare blood clots (preferred term: Thrombosis). On an unknown date, the patient experienced thrombosis (preferred term: Thrombosis).

Action taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable. The patient died from the event of rare blood clots and thrombosis on an unspecified date.

The patient died on an unknown date. The cause of death was rare blood clots and thrombosis. It is not known whether an autopsy was performed.

The events of rare blood clots and thrombosis were considered serious by reporter due to serious criterion of death.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca on 11-OCT-2021 from consumer originating from a spontaneous report: A new reporter of Reporter Regulatory authority was added, a new event of thrombosis was added. Corrected report 13-OCT-2021: Action take for suspect drug was changed from unknown to not applicable, positive dechallenge was updated accordingly.CAUSE OF DEATH: RARE BLOOD CLOTS CAUSE OF DEATH: THROMBOSIS
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal event of Thrombosis (reported as: RARE BLOOD CLOTS and THROMBOSIS) are not listed in the company core sheet for AZD1222. Cause of death is reported as Rare blood clots and Thrombosis. Due to limited information on baseline health conditions before vaccination, date of vaccination and onset dates of events, patient's demographics, concomitant medications, relevant medical history (deep venous thrombosis, traumatic injury, thrombophilia, arrythmia, neoplastic disease, venous insufficiency), family history of thromboembolism, concurrent conditions (such as chronic obstructive pulmonary disease, congestive heart failure, autoimmune diseases, COVID-19 disease, previous surgery), clinical course, further clarification of the events, specific risk factors (prolonged immobilization, smoking, obesity, recent surgery, contraceptive pills or hormone replacement therapy), etiological and diagnostic work up (pneumonologist and cardiologist consulting, complete blood analysis with coagulation profile, electrocardiogram, echocardiography, antithrombin III, protein C and Protein S count, lupus anticoagulant, fibrin degradation products, Dimer D test, COVID-19 test, pulmonary and brain images), autopsy report, the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04270655 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210719 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021605536(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210526 CCYYMMDD	20210709 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) CA-PFIZER INC-2021605536

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Pfizer PFIZERINC	CA-PFIZER INC-2021607041 CA-PFIZER INC-2021605536

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			72 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04270655 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Thrombosis cerebral

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EX0904	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
156 Hours	156 Hours	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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Canada Vigilance AER#:	E2B_04270655 (1)	Page#3
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lost consciousness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lost consciousness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Thrombosis cerebral	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Thrombosis cerebral	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04270655 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOT IN THE RIGHT HEMISPHERE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis cerebral		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
156 Hours	156 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MASSIVE HEADACHE/EXCRUCIATING HEAD PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
156 Hours	156 Hours	Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOST CONSCIOUSNESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lost consciousness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Loss of consciousness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
156 Hours	156 Hours	Not recovered/not resolved	

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04270655 (1)	Page#5

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (patient's partner). A 72-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, lot number EX0904; Expiration date: unknown) intramuscular, administered in deltoid left on [redacted]2021 12:00 as dose 1, single (at the age of 72-year-old) for covid-19 immunisation. Medical history included ongoing diabetic type 2 from 2006 (onset 2006 until death), plugged arteries (not sure) onset unknown and heart surgery in Apr2020. The patient's concomitant medications were not reported. Facility where the most recent COVID-19 vaccine was administered: Public Health Clinic/Veterans Administration facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Consumer was writing this report on behalf of the deceased partner, (privacy). On [redacted]2021, (privacy) received his first PFIZER vaccine at (privacy) centre. On [redacted]2021, (privacy) complained of a massive headache for which he took 2 tablets of paracetamol (TYLENOL). He then lost consciousness. 911 was called and the Emergency Responders took (privacy) to the Hospital. CT Scan indicated that (privacy) had a large blood clot in his brain. An open-brain surgery was conducted, but (privacy) had never his consciousness. He subsequently was transferred to the Hospice where (privacy) died at 5:10 p.m. on [redacted]2021. (privacy) had no prior medical history of blood clot. PRIVACY called to report his partner's death after he received the bnt162b2 vaccine 7 days prior. Blood clot in the right hemisphere leading to death onset[redacted]2021 with seriousness reported as resulted in death. Required visit to emergency room. Outcome fatal. Treatment with brain surgery. Consumer called to report the death of his partner (reporter insisted on giving his partner's full name) after receiving the first dose of the bnt162b2. He called and left a voice message at 8:29am [redacted]2021 and was called back at 11:20am. He confirmed that his partner received bnt162b2 on [redacted]2021. On [redacted]2021, his partner woke up with excruciating head pain. He took 2 paracetamol and laid down on the couch. At that point he was unconscious. Reported called 911 and his partner was taken to the hospital. During brain surgery they found a blood clot in his right hemisphere. Apparently the clot was so big that it crushed the left hemisphere. Reporter does not think there was an autopsy done but was not sure. His partner has type 2 diabetes since 2006 and had a heart surgery in Apr2010 due to plugged arteries but the reporter is not sure. He said he did not have any history of blood clots. The reporter says he knew he was taking medications but did not know which ones exactly. The adverse event result in emergency room/department or urgent care. The treatment was received for the adverse event included (privacy) received an open-brain surgery. The patient was hospitalized for 11 days. Since the vaccination, the patient had not been tested for COVID-19. The patient died on [redacted]2021. It was unknown if an autopsy was performed.

Follow-up (06Jul2021): Follow-up attempts are completed. No further information is expected.

Follow Up (09Jul2021) The following information was received via fax from a contactable Health Care professional (Physician) includes: Deceased [redacted]2021. It is unknown if autopsy was performed.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

There is reasonable possibility of causal association between the events of cerebral thrombosis, headache and loss of consciousness and the drug as (BNT162B2) is known to increase the risk of thromboembolic events. The patient's medical history of Diabetes Mellitus and plugged arteries are confounding factors for the events.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer. procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
	CT scan	indicated that (privacy) had a large blood clot in

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes

Results of tests and procedures (B.3.2)

Computerised tomogram():indicated that (privacy) had a large blood clot in his brain

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Diabetes mellitus	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2006 CCYY	Yes	

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Arterial obstruction NOS

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
25.0	Surgery

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
201004 CCYYMM		201004 CCYYMM

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
25.0	Thrombosis cerebral

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04282284 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210719 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021619262(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210527 CCYYMMDD	20210707 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021619262

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021619262

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04253369, (2) E2B_04253369, (2) E2B_04253369, (2) E2B_04253369, (2) E2B_04253369, (2) E2B_04253369

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	GI bleed

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19 virus test positive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19 virus test positive	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	GI bleed	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	GI bleed	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

GI BLEED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	GI bleed		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Gastrointestinal haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

1 RESIDENT WHO TESTED POSITIVE DIED-ALSO FULLY VACCINATED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug ineffective		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug ineffective		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

1 RESIDENT WHO TESTED POSITIVE DIED-ALSO FULLY VACCINATED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	COVID-19 virus test positive		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	SARS-CoV-2 test positive		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable nurse and physician via a Pfizer sales representative. This nurse and physician reported similar events for 17 patients including 13 residents (12 were fully vaccinated in which 1 died, and 1 received the first dose) and 4 staffs (3 were fully vaccinated and 1 received the first dose). This is the 12th of 17 reports corresponding to the resident who was fully vaccinated and died.

A patient of unspecified age and gender received the second dose and first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date were not provided), both via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. One (1) resident who tested positive died was also fully vaccinated on an unspecified date. The resident who died did not die from COVID though. GI bleed was put as cause. The course of events was as follows: A COVID-19 outbreak was reported post vaccination with patient's experiencing mild to moderate symptoms. So far, they have 7 positive staff in which 3 were fully vaccinated, 3 were not vaccinated, and 1 received the first dose 4 days prior to testing positive. They also have 15 positive residents, 2 were not vaccinated, 1 received the first dose, and 12 were fully vaccinated. 1 resident who was fully vaccinated and tested positive, died and 1 person required high dose dexamethasone. All positive staffs and residents were vaccinated with Pfizer. It was not reported if an autopsy was performed. The outcome of the other events was unknown.

Information on the lot/batch number has been requested.

Follow-up (07Jul2021): This follow-up is being submitted to notify that the batch/lot number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

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MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The patient received full dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on unspecified dates and tested positive, and died from gastrointestinal (GI) bleeding. Based on the information currently available, a lack of efficacy with the suspected vaccine BNT162B2 in this patient was possible. However, the fatal event (GI) bleeding was unlikely causally related to the vaccine of BNT162B2. Further information like vaccination/COVID infection date, medical history and clinical course needed for a meaningful medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	SARS-CoV-2 test	positive	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	GI bleed	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04284001 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211028 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-199641(2)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 202[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 2021[redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) Yes		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2021-199641

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) irms QMODERNAP	**Duplicate Case identifiers (A.1.11.2)** CA-irms-MDCA21-01515 CA-MODERNATX, INC.-MOD-2021-199641

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) 000960069, (1) 000980575

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 71 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04284001 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Activities of daily living impaired	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Activities of daily living impaired	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Clot blood	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Parsonage-Turner syndrome	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Parsonage-Turner syndrome	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Psychomotor retardation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Psychomotor retardation	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Shingles	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Strength loss of	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Strength loss of	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swollen arm	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swollen arm	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vaccination site movement impairment	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vaccination site movement impairment	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Weight loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Provided
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Weight loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) PREDNISONE	
Active Substance names (B.4.k.2.2) prednisone		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 7.5 Milligram		
Dosage text (B.4.k.6) 7.5 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METFORMIN	
Active Substance names (B.4.k.2.2)		
metformin		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
500 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6)		
500 mg, bid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ATORVASTATIN	
Active Substance names (B.4.k.2.2) atorvastatin		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 1 Dosage forms		
Dosage text (B.4.k.6) 1 dosage form at bed time		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ONE ALPHA	
Active Substance names (B.4.k.2.2) alfacalcidol		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) .25 Microgram		
Dosage text (B.4.k.6) 0.25 mcg At bedtime		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) PREGABALIN	
Active Substance names (B.4.k.2.2) pregabalin		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 25 Milligram		
Dosage text (B.4.k.6) 25 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	BENSERAZIDE HYDROCHLORIDE/LEVODOPA	
Active Substance names (B.4.k.2.2)		
benserazide hydrochloride levodopa		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
25 Milligram		
Dosage text (B.4.k.6)		
25 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RISEDRONATE	
Active Substance names (B.4.k.2.2)		
risedronate sodium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02370239 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
35 Milligram		
Dosage text (B.4.k.6)		
35 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	HYDRALAZINE	
Active Substance names (B.4.k.2.2)		
hydralazine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02370239 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
25 Milligram,3 every 1 (Days)		
Dosage text (B.4.k.6)		
25 mg, tid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) CARVEDILOL	
Active Substance names (B.4.k.2.2) carvedilol		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 12.5 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6) 12.5 mg, bid		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	AMLODIPINE	
Active Substance names (B.4.k.2.2)		
amlodipine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) CALCIUM	
Active Substance names (B.4.k.2.2) calcium		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) 1 UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PANTOPRAZOLE SODIUM	
Active Substance names (B.4.k.2.2)		
pantoprazole sodium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MAGNESIUM	
Active Substance names (B.4.k.2.2)		
magnesium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
250 Milligram		
Dosage text (B.4.k.6)		
250 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted] CCYYMM	2021[redacted] CCYYMM	

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

CLOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
2 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PARSONAGE-TURNER SYNDROME

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Parsonage-Turner syndrome		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Neuralgic amyotrophy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
2 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHINGLES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Shingles		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Herpes zoster		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
2 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE IS UNABLE TO DO HIS ACTIVITIES OF DAILY LIVING SUCH AS DRIVING, BATHING, FEEDING, OR DRESSING HIMSELF'

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Activities of daily living impaired		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Loss of personal independence in daily activities		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
2 Days		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LACKED STRENGTH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Strength loss of
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Asthenia

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 199 Days	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PSYCHOMOTOR RETARDATION

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Psychomotor retardation
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Psychomotor retardation

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 199 Days	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNABLE TO MOVE ARM

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Vaccination site movement impairment
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Vaccination site movement impairment

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 2 Days	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ARM IS SWOLLEN

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Swollen arm
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Peripheral swelling

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4) 2021[redacted]	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 2 Days	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WEIGHT LOSS

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Weight loss
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Weight decreased

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This spontaneous case was reported by a nurse and describes the occurrence of DEATH (Death), THROMBOSIS (Clot), NEURALGIC AMYOTROPHY (Parsonage-Turner Syndrome), HERPES ZOSTER (Shingles), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (He is unable to do his activities of daily living such as driving, bathing, feeding, or dressing himself'), ASTHENIA (Lacked strength), PSYCHOMOTOR RETARDATION (Psychomotor retardation), VACCINATION SITE MOVEMENT IMPAIRMENT (unable to move arm), PERIPHERAL SWELLING (arm is swollen) and WEIGHT DECREASED (weight loss) in a 71-year-old male patient who received mRNA-1273 (Moderna CovID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination.

No medical history was provided by the reporter.
Concomitant products included PREDNISONE, METFORMIN, ATORVASTATIN, ALFACALCIDOL (ONE ALPHA), PREGABALIN, BENSERAZIDE HYDROCHLORIDE, LEVODOPA (PROLOPA), RISEDRONATE SODIUM (RISEDRONATE), HYDRALAZINE, CARVEDILOL, AMLODIPINE, CALCIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOLOC) and MAGNESIUM for an unknown indication.

On [redacted] 2021, the patient received first dose of mRNA-1273 (Moderna CovID-19 Vaccine) (Intramuscular) 1 dosage form. On [redacted] 2021, the patient experienced THROMBOSIS (Clot) (seriousness criteria hospitalization and medically significant), NEURALGIC AMYOTROPHY (Parsonage-Turner Syndrome) (seriousness criterion hospitalization), HERPES ZOSTER (Shingles) (seriousness criterion hospitalization), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (He is unable to do his activities of daily living such as driving, bathing, feeding, or dressing himself') (seriousness criterion hospitalization), VACCINATION SITE MOVEMENT IMPAIRMENT (unable to move arm) (seriousness criterion hospitalization) and PERIPHERAL SWELLING (arm is swollen) (seriousness criterion hospitalization). On [redacted] 2021, the patient experienced ASTHENIA (Lacked strength) (seriousness criterion hospitalization) and PSYCHOMOTOR RETARDATION (Psychomotor retardation) (seriousness criterion hospitalization). On an unknown date, the patient experienced WEIGHT DECREASED (weight loss) (seriousness criterion hospitalization). The patient died in [redacted] 2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, THROMBOSIS (Clot), NEURALGIC AMYOTROPHY (Parsonage-Turner Syndrome), HERPES ZOSTER (Shingles), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (He is unable to do his activities of daily living such as driving, bathing, feeding, or dressing himself'), ASTHENIA (Lacked strength), PSYCHOMOTOR RETARDATION (Psychomotor retardation) and WEIGHT DECREASED (weight loss) outcome was unknown and VACCINATION SITE MOVEMENT IMPAIRMENT (unable to move arm) and PERIPHERAL SWELLING (arm is swollen) had resolved.

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):
On an unknown date, Weight: 15 pounds (Low) 15 pounds.

For mRNA-1273 (Moderna CovID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.

Treatment medication included antiviral (name unspecified).
The patient was hospitalized for 7 days starting one day post vaccination. Patient experienced severe pain, clot, unable to move his arm, shingles and was diagnosed with Parsonage-Turner Syndrome. Nurse stated that patient's arm is swollen presently and bandages had to be changed 3-4 times per day due to leaking. Leaking has diminished some. The patient is unable to use his left arm. He is unable to do his activities of daily living such as driving, bathing, feeding, or dressing himself.

The symptoms of the patient's were improved. The patient almost had no more swelling, able to move his arm, but with less force, still had pain in the hand. But his general condition declined since the vaccination.

On [redacted] 2021, the patient had marked psychomotor retardation and lacked strength. He wasn't able to get up of his chair without help. So patient was sent to the hospital (unspecified date).

On [redacted] 2021, the nurse learnt that patient was died due to unknown cause of death.
This case concerns a death of a 71-year-old, male patient with no relevant medical history, who experienced the unexpected events of thrombosis, neuralgic amyotrophy, h erpes zoster, loss of personal independence in daily activities, vaccination site movement impairment, asthenia, psychomotor retardation, weight loss and peripheral swelling. The events occurred approximately 1 day after the first dose of Moderna COVID-19 Vaccine with exception of asthenia, psychomotor retardation and death which occurred approximately 7 months after the first dose. The patient was initially hospitalized for 7 days, for severe pain, clot, unable to move his arm, shingles, being unable to do his activities of daily living, starting one day post vaccination with Moderna COVID 19 vaccine. The patient was diagnosed with Parsonage-Turner Syndrome. Since then the symptoms were improved and the patient almost had no more swelling, able to move his arm,

Most recent FOLLOW-UP information incorporated above includes:
On [redacted] 2021: FU Received on [redacted] 2021, Three new events lacked strength, he lost weight, about 15 pounds added. Death date was added.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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This case concerns a death of a 71-year-old, male patient with no relevant medical history, who experienced the unexpected events of thrombosis, neuralgic amyotrophy, herpes zoster, loss of personal independence in daily activities, vaccination site movement impairment, asthenia, psychomotor retardation, weight loss and peripheral swelling. The events occurred approximately 1 day after the first dose of Moderna COVID-19 Vaccine with exception of asthenia, psychomotor retardation and death which occurred approximately 7 months after the first dose. The patient was initially hospitalized for 7 days, for severe pain, clot, unable to move his arm, shingles, being unable to do his activities of daily living, starting one day post vaccination with Moderna COVID 19 vaccine. The patient was diagnosed with Parsonage-Turner Syndrome. Since then the symptoms were improved and the patient almost had no more swelling, able to move his arm, but with less force, still had pain in the hand. However,, approximately 7 months after the first dose the patient had marked psychomotor retardation and lacked strength due to which patient was sent to the hospital. The pateint died due to unknown cause of death. No autopsy results were provided. The rechallenge was not applicable as it was not reported that the patient received the second dose before death. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Weight	15 pounds	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
OTHER			Yes

Results of tests and procedures (B.3.2)

Weight;;15 pounds;15 pounds

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

No medical history was provided by the reporter.

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04285882 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210614 CCYYMMDD	
	HC Initial Received Date: 20210614 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2021AMR102648(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 202[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20210611 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-GLAXOSMITHKLINE-CA2021AMR102648

Other case identifiers in previous transmission? (A.1.11) Yes

Duplicate Source(s) (A.1.11.1) 01052547635	**Duplicate Case identifiers (A.1.11.2)** CA-GLAXOSMITHKLINE-CA2021AMR102648

Duplicate (D) / Link (L) Report number(s) (A.1.12) (2) E2B_04022832, (2) , (2) , (2) , (2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14) Yes

Source (A.1.4) MAH - GLAXOSMITHKLINE

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 52 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	MEPOLIZUMAB	
Active Substance names (B.4.k.2.2)		
mepolizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	L64H	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
100 Milligram		
Dosage text (B.4.k.6)		
100 mg, Z, every 4 weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Eosinophilic asthma
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2019[redacted] CCYYMMDD	202[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		615 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
ExpDT=??-JUL-2024		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unknown
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Injection related reaction	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Injection related reaction	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted] CCYYMM	2021[redacted] CCYYMM	1 Months
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT HAD INJECTION REACTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Injection related reaction		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Injection related reaction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
615 Days		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This case was reported by a nurse via (Vista Patient Support Program (Nucala)) patient support programs and described the occurrence of injection related reaction in a 52-year-old male patient who received mepolizumab powder for injection (batch number L64H, expiry date July 2024) for eosinophilic asthma.

Co-suspect products included pfizer-biontech covid-19 vaccine for covid-19 prophylaxis.

On [redacted] 2019, the patient started mepolizumab (subcutaneous) 100 mg (every 4 weeks). On [redacted] May 2021, the patient started pfizer-biontech covid-19 vaccine (intramuscular) at an unknown dose and frequency. On [redacted] 2021, 615 days after starting mepolizumab, the patient experienced injection related reaction. The action taken with mepolizumab was unknown. On an unknown date, the outcome of the injection related reaction was unknown.

It was unknown if the reporter considered the injection related reaction to be related to mepolizumab.

Additional details:
The drug mepolizumab used by the patient was Nucala. Patient clarified with manager about covid vaccine, patient had his Pfizer IM on[redacted] per manager, okay to give injection still today. Patient had injection reaction. Further information had been requested regarding the injection reaction. This case had been linked with CA2021AMR066178, CA2020AMR012765, CA2019AMR192512, CA2019AMR151119 and CA2019AMR149288. It was unknown if the reporter considered the injection related reaction to be related to PFIZER-BIONTECH COVID-19 VACCINE.

Follow up information was received via a consumer on [redacted] 2021:
In[redacted]2021, the patient experienced death (serious criteria death and GSK medically significant). In[redacted]2021, the outcome of the death was fatal. The subject died in[redacted]2021. The reported cause of death was unknown cause of death. It was unknown if the reporter considered the death to be related to mepolizumab and pfizer-biontech covid-19 vaccine. The autopsy information was unknown. Patient's wife reported that the patient passed away 2 weeks ago. The patient's wife did not disclose any other information. Patient's last Nucala injection was [redacted] 2021.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04285882 (0)	Page#7

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Mepolizumab Patient Support Program	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
Mepolizumab PSP	Other studies

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04304553 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210630 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021677008(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210609 CCYYMMDD	20210615 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021677008

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021677008

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			95 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04304553 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 202[redacted] CCYYMM	**Drug end date (B.4.k.14)** 202[redacted] CCYYMM	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Unknown cause of death	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04304553 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Unknown cause of death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable pharmacist (patient's family member). A 95-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: unknown), via unknown route of administration on [redacted]2021 (at the age of 95 years old) as dose 1, single for COVID-19 immunisation. Medical history included didn't have any comorbidities but had a pacemaker, a strong magnet had to be used to disactivate pacemaker by paramedic to reinitiate his rhythm. The patient's concomitant medications were not reported. Patient passed away on [redacted]2021 (also reported as on [redacted]2021 or [redacted]2021) exactly 3 weeks after patient received his first dose (the day he was supposed to receive his 2nd dose). He only received 1st dose. The patient underwent lab tests and procedures which included antibody test to platelet factor IV with unknown results. The patient died on [redacted]2021. It was unknown if autopsy was performed.

Information about lot/batch number was requested.

Follow-up (15Jun2021): New information received from a contactable pharmacist via fax includes: patient details (age at vaccination), suspect drug details (updated trade name and vaccination date), event details (death date), and laboratory data.

No follow-up attempts are possible, information about batch number cannot be obtained.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Information provided is limited and does not allow a thorough medical assessment of this fatal case. Causality cannot be completely excluded for the ongoing treatment with suspect drug according to Company internal procedure for cases reporting death cause unknown.
The impact of this report on the benefit/risk profile of the Pfizer drugs is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Platelet factor 4	Unknown result	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac pacemaker insertion	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04331530 (4)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220126 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021665581(5)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220114 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	Yes
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-2021665581

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-2021665581

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04933226, (2) , (2) , (2) , (2) , (2) E2B_04933226, (2) E2B_04933226

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1) 21 Weeks		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04331530 (4)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cardiac septal defect
26.0	Coarctation of the aorta
26.0	Congenital heart disease NOS
26.0	Double inlet left ventricle
26.0	Maternal exposure during pregnancy, first trimester

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)
26.0	Cardiac septal defect
26.0	Coarctation of the aorta

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3) E L0203 CC02	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Transplacental	Parent route of admin (B.4.k.9) Intramuscular
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	Drug end date (B.4.k.14) 202[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		

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Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coarctation of the aorta	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Coarctation of the aorta	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Double inlet left ventricle	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Double inlet left ventricle	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart disease congenital	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart disease congenital	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ventricular septal defect	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Ventricular septal defect	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	N/A

Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** DICLECTIN	
Active Substance names (B.4.k.2.2) pyridoxine hydrochloride doxylamine succinate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 00609129 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK, 2x/day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Transplacental	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Nausea
Start date of drug (B.4.k.12) 202[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)** 52 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FOLIC ACID	
Active Substance names (B.4.k.2.2) folic acid		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 800 Milligram 1 (Days)		
Dosage text (B.4.k.6) 800 mg, daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Transplacental	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Prenatal care
Start date of drug (B.4.k.12) 2018 CCYY	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	OMEGA 3 [FISH OIL]	
Active Substance names (B.4.k.2.2)		
FISH OIL		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Dosage forms 1 (Days)		
Dosage text (B.4.k.6)		
1 DF, daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Transplacental	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Prenatal care
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2020 CCYY		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MATERNAL EXPOSURE DURING PREGNANCY, FIRST TRIMESTER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Maternal exposure during pregnancy, first trimester		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Maternal exposure during pregnancy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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SEVERE CONGENITAL HEART DISEASE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Heart disease congenital
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Heart disease congenital

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DOUBLE INLET LEFT VENTRICLE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Double inlet left ventricle
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Double inlet left ventricle

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LARGE VENTRICULAR SEPTAL DEFECT (CARDIAC DEFECT IN BABY) / PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Ventricular septal defect
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Ventricular septal defect

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CO-ARCTATION OF THE AORTA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Coarctation of the aorta
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Coarctation of the aorta

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from contactable physicians (one is the mother) via COVAES. This physician reported information both for the mother and fetus. This is the fetus report. A fetus female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 transplacental on [redacted]2021, 13:00 (Batch/Lot Number: E L0203 CC02) as dose 1, single; and dose 2 transplacental, on [redacted]2021, 10:00 (Batch/Lot Number: EW0193) as dose 2, single for covid-19 immunisation. The 33-year-old mother had received both doses of the bnt162b2 vaccine during pregnancy. Medical history was not reported. The mother's concomitant medication included doxylamine succinate, pyridoxine hydrochloride (DICLECTIN) taken for nausea from [redacted]2021 to [redacted]2021; folic acid taken as routine prenatal care from 2018, fish oil (OMEGA 3) taken for routine prenatal care from 2020 and prenatal vitamin routine prenatal cares in 2018 with 4 gummies per day. On [redacted]2021, the patient experienced Maternal exposure during pregnancy, first trimester. In [redacted]2021, the patient experienced severe congenital heart disease. The event severe congenital heart disease required visit to physician office/ hospital admission. It was reported that the mother of the

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patient was given 1st dose in 1st trimester of pregnancy which resulted in severe congenital heart disease identified. There was no other cause identified. On an unspecified date, the patient experienced large ventricular septal defect (cardiac defect in baby) and double inlet left ventricle. First dose was given at time of cardiogenesis link and large ventricular septal defect. The events were considered serious due to congenital anomaly. The mother had a genetrics consult on [redacted]021. The mother had any problems before delivery which included severe cardiac defeat, pregnancy ended. Mother had a caesarian section at 21 weeks fetal demise and was sent for autopsy. Induced abortion on [redacted]2021 with gestational age at 21 weeks. Patient had a congenital malformation: double inlet left ventricle CHO. Reason of termination included double inlet left ventricle and severe congenital heart disease at 21 weeks. Laboratory tests and procedures included panorama, general testing and microdeletion panel on [redacted]2021 showed low risk no trisomy or microdeletion identified; fetal echocardiogram on [redacted]2021 showed double inlet left ventricle/ severe cardiac defect and amniocentesis on [redacted]2021 showed normal CMA/ no (illegible in chromosome analysis), fetal cardiac scan by MFM in [redacted]2021 showed fetal cardiac defect, and routine fetal anatomy scan on [redacted]2021 (cardial defect, otherwise normal). The mother also underwent ante natal check-up which included multiple noninvasive prenatal screening (NIPS) (panorama test) on [redacted]2021 was normal and weekly ultrasound with maternal fetus medicine was normal cervical length. The father of the patient was drinking during mother's pregnancy which included 1/2 units daily. Outcome of Large ventricular septal defect (cardiac defect in baby) was unknown. The patient died on [redacted]2021 due to severe congenital heart disease and maternal exposure during pregnancy, first trimester and double inlet left ventricle. On [redacted]2021, reported results of serology: rubella immune. Ante natal check-up: Multiple NIPS (panorama test) [redacted]2021. Normal, Weekly ultrasound with maternal fetal medicine (MFM) - normal cervical length, Routine fetal anatomy scan [redacted]2021 (cardiac defect, otherwise normal), Fetal cardiac scan by MFM [redacted]2021, fetal cardiac defect, genetics consult [redacted]2021, fetal echo [redacted]2021 -double inlet in left ventricle. An autopsy was performed, and results were provided. Additional information on 14Jan2022: Autopsy results: Normal beyond congenital heart disease. Double inlet left ventricule. Normal complete exome sequence. Narrative: Complete autopsy done- only cardiac anomalies identified. Congenital cardiac malformation, with double outlet left ventricule, perimembranous ventricular septal defect and co-arctation of the aorta.
Investigation results included Brief complaint description: Product quality investigation request lot number EL0203 CC02 and EW0193 Adverse event: Severe congenital heart disease, date: [redacted]2021, seriousness criteria: resulted in fetal death, AE required visit to: Physicians office/ hospital admission, Outcome; fatal [redacted]2021 fetal disease, treatment: unknown. Comments: 33 years old patient 1st dose given in 1st trimester of pregnancy. Resulting severe congenital heart disease identified. no other cause identified. QAEF attached FDA 15-Day report. PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE- EW0193- Adverse Event Safety Request For Investigation. Reasonably Suggest Device Malfunction was No. Severity of Harm: NA. Root Cause: Process Related: No, Final Confirmation Status: Not Confirmed, Vendor Related: No. Lot-Specific Trend Identified: No. Lot Trend Assmt. & Rationale: The complaint history for the reported PFIZER-BIONTECH. COVID-19 VACCINE lot EW0193 was reviewed. As of July 19, 2021, this is the only complaint for this lot and classification. No lot specific trend was identified that would require additional investigation. Lot Trend Actions Taken: There were no lot trend actions taken as a result of this investigation. Site Sample Status: Not Received. Summary of Investigation from Kalamazoo (EP) division was: The initial scope of the investigation was limited to the reported finished goods lot EW0193, fill lot EP8739, and the bulk formulated drug product lot EP8620. Based on the results of this investigation, the scope was not expanded. Manufacturing and packaging batch records were examined. There were no planned or unplanned deviations recorded during the manufacture of the lot that may have impacted product quality. Pfizer Kalamazoo QO did not receive a complaint sample or photographs for examination. The complaint was not confirmed. No related quality issues were identified during the investigation. There were no planned or unplanned deviations recorded during the manufacture of the lot that were determined to have an impact on product quality. A review of the manufacturing and packaging records confirmed all processing steps met established requirements, all noted defects were within limits and discarded, elapsed time tracking was within limits, and the freezer storage was acceptable. There were no product quality defects observed during the examination of retained reference samples. There is no impact to the quality of the lot. It is unknown how the product was handled, stored, or administered after it left the Kalamazoo site. Investigational report conclusion from Kalamazoo (EP) division was: The complaint for an adverse event requested by safety with the use of the PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE lot EW0193 was investigated. The investigation included reviewing the manufacturing and packaging batch records, retained reference samples, deviation investigations and an analysis of the complaint history for the reported lot. The final scope was determined to be the reported finished goods lot EW0193, fill lot EP8739, and the bulk formulated drug product lot EP8620. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality. No root cause or CAPA were identified as the complaint was not confirmed. Product quality investigation request lot number EL0203 CC02 and EW0193. Adverse event: Severe congenital heart disease, date: [redacted]021, seriousness criteria: resulted in fetal death, AE required visit to: Physicians office/ hospital admission, Outcome; fatal [redacted]2021 fetal disease, treatment: unknown.

Product quality investigation request lot number EL0203, Adverse event: Severe congenital heart disease, date: [redacted]2021, seriousness criteria: resulted in fetal death, Root Cause: Process Related: No, Final Confirmation Status: Not Confirmed, Vendor Related: No. Lot-Specific Trend Identified: No. Site Sample Status: Not Received. Investigational report conclusion from Puurs division was: For this lot Adverse Event Safety Request For Investigation and/or Lack Of Effect was previously investigated. A sample was not sent to the QC-lab to determine the amount of active ingredient since the complaint was received within six months after the release date of the involved batch. All analytical results were checked and were within registered limits. The investigation of the referenced PR ID resulted in the following conclusion: Reference PR ID 5788999 (see File attachment in this investigation record). The complaint for "PFIZER-BIONTECH COVID-19 VACCINE" was investigated. The investigation included reviewing the involved batch records, deviation investigation and an analysis of the complaint history for the reported lot and product type. The final scope was determined to be the associated lot(s) of the reported lot EL0203. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation and stability. PGS Puurs concludes that the reported defect is not representative of the quality of the batch and the batch remains acceptable. The NTM process determined that no regulatory notification was required. The reported defect could not be confirmed. No root cause or CAPA were identified as the complaint was not confirmed.

Follow-up (18Jun2021): New information received from the same contactable physician via a completed HCP questionnaire, includes: patient details (mother information updated), product details (dosing regimen updated), and clinical course of events added.

Follow-up (13Jul2021): Follow-up attempts are completed. No further information is expected.

Follow-ups (25Aug2021): New information from product compliant group included investigation results.

No follow up attempts are needed. No further information is expected.

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Follow-up (10Nov2021): New information received from a contactable physician includes lab data and suspect drug details (updated dose 2 date).

No follow-up attempts are needed. No further information is expected.

Follow-up (14Jan2022): This is a spontaneous report received from a contactable reporter (Nurse).
Updated information included: New reporter, Autopsy results available: Yes, Cause of death and autopsy results section, event (coarctation of the aorta).

No follow-up attempts are needed. No further information is expected.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on temporal association, the causal relationship between BNT162B2 and the reported events cannot be completely ruled out. The impact of this report on benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethic committees, and Investigators, as appropriate.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
202005 CCYYMM	Physical examination	fetal cardiac defect	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2021[redacted] CCYYMMDD	Investigation	low risk	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2021[redacted] CCYYMMDD	Investigation	normal	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2021[redacted] CCYYMMDD	Physical examination	cardiac defect, other wise normal	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2021[redacted] CCYYMMDD	Investigation	low risk	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2021[redacted] CCYYMMDD	Investigation	normal CMA	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
2021[redacted] CCYYMMDD	Investigation	severe cardiac defect	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
202[redacted] CCYYMM	Investigation NOS	Unknown results	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
	Ultrasound scan	normal cervical length	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			Yes

Results of tests and procedures (B.3.2)

Investigation[redacted]2021):Genetic testing and microdeletion panel

no trisomy or microdeletions identified
Ultrasound scan():weekly with Maternal Fetal Meicine
Investigation[redacted]2021):no trisomy or microdeletion identified
Investigation[redacted]2021):no trisomy or microdeletion identified.
normal
Investigation[redacted]2021):no trisomy or microdeletion identified
Investigation[redacted]2021):double inlet left ventricle/ severe cardiac defect
Investigation[redacted]2021):no deletion or addition (illegible) in chromosome analysis.

Whole exome sequence pending

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Double inlet left ventricle	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Maternal exposure during pregnancy, first trimester	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congenital heart disease NOS	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Coarctation of the aorta	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac septal defect	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
		33 Years	
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	
146 Kilogram	160 Centimeter	Female	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)
v.26.0	Cervix cerclage procedure

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
202010 CCYYMM		

Comments (B.1.10.7.1g)
Surgically repaired and abdominal cerclage Oct2020.

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)
v.26.0	Cervix disorder

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)
has abdominal cerclage with no (illegible)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)
v.26.0	Multigravida

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)
Number of previous pregnancies: 2

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	**Observed study type (A.2.3.3)**

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04336566 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211126 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A557253()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210623 CCYYMMDD	20211121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	Company number (A.1.10.2) CA-AstraZeneca-2021A557253

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	E2B_04336566 [redacted] CA-AstraZeneca-2021A557253

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female	168 Centimeter	90.3 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1966[redacted] CCYYMMDD			55.23 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04336566 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Deep vein thrombosis
26.0	Pulmonary embolism

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)
26.0	Deep vein thrombosis
26.0	Pulmonary embolism

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml Cumulative dose to first reaction: .5 ml		
Dosage text (B.4.k.6)		
Dose 1 0.5mL ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
1 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Dosage maintained		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Deep vein thrombosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
INITIAL REPORTER		Yes
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulmonary embolism	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
INITIAL REPORTER		Yes

ATIA - 19(1)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PULMONARY EMBOLISM

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary embolism		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pulmonary embolism		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No	2021[redacted]		2
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
1 Days		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PELVIC DEEP VEIN THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Deep vein thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Deep vein thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No	2021[redacted]		2
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
1 Days		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer concerning a 55-year old female patient of Caucasian ethnic origin with height 66 in and weight 199 lb.

No medical history was reported. No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (Dose 1, batch number UNKNOWN) 0.5 ml once/single administration, via intramuscular route, on [redacted]2021. On [redacted]2021, the patient experienced pulmonary embolism (preferred term: Pulmonary embolism) and pelvic deep vein thrombosis (preferred term: Deep vein thrombosis).

Treatment with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not changed.

The patient died from the event of pulmonary embolism and pelvic deep vein thrombosis on [redacted]2021.An autopsy was performed. The cause of death was pulmonary embolism with pelvic deep vein thrombosis (confirmed at autopsy) and pulmonary embolism with pelvic deep vein thrombosis (confirmed at autopsy).

The events were considered serious due to seriousness criteria of death and important medical event.

The reporter considered the following event(s) related to treatment with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml: pelvic deep vein thrombosis and pulmonary embolism.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order

Summary of follow-up information received by AstraZeneca 21-Nov-2021, a spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer: New reporter regulatory authority was added. frequency was updated in product tab. Associated case ID added in case tab. Narrative updated.AUTOPSY DETERMINED CAUSE OF DEATH: PULMONARY EMBOLISM WITH PELVIC DEEP VEIN THROMBOSIS AUTOPSY DETERMINED CAUSE OF DEATH: PULMONARY EMBOLISM WITH PELVIC DEEP VEIN THROMBOSIS
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Pulmonary embolism and Deep vein thrombosis (reported as PELVIC DEEP VEIN THROMBOSIS) are not listed in company core data sheet of AZD1222. Due to limited information on the baseline characteristics of the patient, circumstances leading to the events,complete clinical course and management, relevant details on medical history (any history of diabetes,thromboembolic episodes in the past and any history of deep vein thrombosis at other sites), personal and family history of the patient, concurrent diseases,risk factors (smoking, sedentary life style and obesity), etiological and complete diagnostic work up (complete blood picture, coagulation profile, lipid profile, pulmonary angiogram, venous doppler, electrocardiogram and echocardiogram) the evaluation did not find evidence to suggest a causal relationship between the events and the vaccine AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pulmonary embolism	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Deep vein thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) PRIVACY	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) CANADIAN HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) Confidential
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_04336566 (1)	Page#7

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Bonjour, j'ai reçu un courriel de la part de Mme Michelle Séguin suite à ma déclaration initiale. On me demande de préciser certains détails ce que je vais tenter de faire ici mais je n'ai pas les réponses à certaines de vos questions.

Question : Tout traitement médical que mon père a reçu après l'apparition de l'effet indésirable?

Réponse : Mon père n'a reçu aucun traitement médical après son décès. Il est décédé dans la nuit du [redacted] Ma mère l'a trouvé inconscient le matin. Elle a appelé les ambulanciers qui lui ont fait les manœuvres cardiaques. Selon eux, à ce moment là il avait encore une pression et ils disaient que selon eux ce serait neurologique donc peut-être un AVC. Arrivé à l'hôpital il est décédé.

Question : Les résultats de toute enquête médicales (le cas échéant) avant son décès et /ou diagnostic clinique au sujet du AVC soupçonné?

Réponse : Tel que mentionné, aucune autopsie n'a été faite compte tenu de son âge donc il n'y a aucune enquête médicale avant ou après.

Question : Est-ce qu'un spécialiste / md a posé un diagnostic d'accident vasculaire cérébral (AVC)?

Réponse : Non malheureusement.

Question : L'information au sujet du lieu du décès de mon père?

Réponse : Il est décédé à l'hôpital [redacted]

Il n'y a malheureusement aucune autopsie donc je sais qu'il est difficile d'évaluer ce cas. Toutefois, ce que je peux dire est que mon père avait fait un bilan sanguin peu de temps avant et tout était normal. Aucun diabète, aucun cholestérol, etc.

Il était vieillissant mais n'avait aucun antécédent de maladie cardiaque/avc. Il prenait des médicaments pour contrôler le parkinson, pour la dépression et, entre autre, pour la prostate. J'ai déjà fourni précédemment la liste des médicaments qu'il prenait.

Pour plus d'informations, vous pouvez contacter l'hôpital pour obtenir son dossier et/ou son Md de famille : Dr [redacted]

Safety Report ID: CA-DHPR-20210414120458_3786

Type of Report: Suivi

HC Ref. No [redacted]

Reporter File No.:

Transmission Date: 20210414

First Name: [redacted]

Last Name: [redacted]

Telephone: [redacted]

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ATIA - 19(1)

Ext.:

Address [redacted]

City [redacted]

Province/Territory: [redacted]

Postal Code: [redacted]

Email address: [redacted]

Organization:

Reporter Type: Consommateur ou autre non-professionnel de la santé

Patient ID: [redacted]

Age: 89 Année(s)

Sex: Homme

Height: 155 cm

Weight: 55 kg

Med History: non fumeur

Allergies: aucune

Serious Death: Oui

Date of Death: 2021 [redacted]

Serious Life-Threatening:

Serious Disability:

Serious Hospitalization:

Serious Congenital Anomaly:

Serious Other:

Serious Other Explain:

Reaction 1

Outcome: Décédé

Reaction Start Date:

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Reaction End Date:

Reaction Description: Décès

Suspect Product 1

DIN #/NPN #: A4H1K2

Product Name: Vaccin Pfizer-Biontech

Strength: 0 ml millilitre(s)

Strength other:

Dosage form: 0.3ml

Manufacturer: Pfizer

Lot #:

Expiry date:

Product start date:

Product end date:

Dose:

Frequency:

Route of administration:

Route of administration - Other:

Indication:

Reported to Mfr: Oui

Date reported to Mfr: 20210401

Mfr Reference number:

Drug action taken: Inconnu

Dechallenge:

Rechallenge:

Concomitants:

Test/Lab results narrative:

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-04-14 10:18 AM
To: [redacted]
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: Suivie par Santé Canada - Vaccin COVID-19 Pfizer-Biontech

Chère [redacted]

Nous vous remercions et accusons réception de votre déclaration d'effet indésirable soumise au Programme Canada Vigilance le 12 Avril 2021, concernant le produit de santé : Vaccin COVID-19 Pfizer-Biontech.

Veuillez recevoir nos sincères condoléances pour vous et votre famille. Nous comprenons que cette situation doit être difficile et nous apprécions le temps que vous avez pris pour partager cet évènement tragique.

L'information que vous avez fournie dans votre déclaration a été enregistrée dans la base de données du Programme Canada Vigilance sous le numéro d'effet indésirable (NEI) 000945483.

Par conséquent de suivi d'évaluation par Santé Canada, le Programme de Canada Vigilance a identifié cette déclaration pour un suivi.

Canada Vigilance N0	Clarification
000945483 (Date de réception [Santé Canada]): 12/04/2021	Veuillez SVP donnez toute information supplémentaire concernant: • Tout traitement médical que votre père a reçu après l'apparition de l'effet indésirable • Les résultats de toute enquête médicale (le cas échéant) avant son décès et / ou diagnostic clinique au sujet du AVC soupçonné; • Est-ce qu'un spécialiste/ médecin a posé le diagnostic d'accident vasculaire cérébral (AVC) • L'information au sujet du lieu du décès de votre père (l'hôpital/domicile)

Veuillez indiquer le numéro de référence de Santé Canada si vous voulez fournir des renseignements supplémentaires au sujet de cet incident. Nous vous invitons à fournir plus de détails afin de renchérir l'information en lien avec votre déclaration en utilisant l'application de déclaration en ligne disponible pour déclarer un effet secondaire. S'il vous plait, assurez-vous de sélectionner l'option de « suivi » et bien inscrire votre NEI (000945483) aux champs ci-dessous :

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A2023000085

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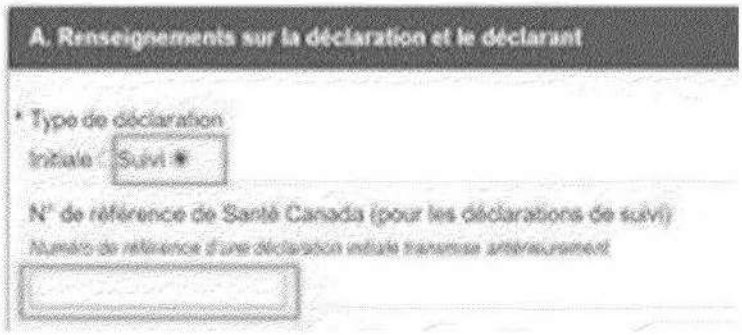

Une réponse dans les meilleurs délais serait grandement apprécié pour l'évaluation de ce cas.

Encore une fois nous souhaitons vous transmettre nos sincères condoléances. N'hésitez pas à contacter le Programme Canada Vigilance si de plus amples informations vous sont nécessaires.

Merci de votre collaboration,

Michelle Séguin
Santé Canada

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
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ATIA - 19(1)

Canada Vigilance AER#:	000945483 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210414 CCYYMMDD
	HC Initial Received Date:	20210412 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR-20210412145858_26367()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
		Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_03986299

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

Community -

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male	155 Centimeter	55 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			89 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021 CCYY	No

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ATIA - 19(1)

Canada Vigilance AER#:	000945483 (1)	Page#2

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML

Active Substance names (B.4.k.2.2)

tozinameran

Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)
	A4H1K2

Holder and authorization/application no. of drug (B.4.k.4)

Authorization/Application no.: 02509210
Country of authorization/application: Canada

Structured dosage info (B.4.k.5)

.3 ml

Dosage text (B.4.k.6)

Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)

Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)

Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)
2021[redacted] CCYYMMDD	

Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
3 Days		

Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)

Additional info (B.4.k.19)

Drug Recurrence (B.4.k.17)

MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)

Drug Reaction relatedness (B.4.k.18)

MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FINASTERIDE	
Active Substance names (B.4.k.2.2) finasteride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) PANTOPRAZOLE	
Active Substance names (B.4.k.2.2) pantoprazole		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) AURO-MIRTAZAPINE OD	
Active Substance names (B.4.k.2.2) mirtazapine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) APO-LEVOCARB	
Active Substance names (B.4.k.2.2) carbidopa levodopa		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TAMSULOSIN CR	
Active Substance names (B.4.k.2.2) tamsulosin hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TEVA-LOPERAMIDE	
Active Substance names (B.4.k.2.2) loperamide hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02132591 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SELON LES AMBULANCIERS CE SERAIT NEUROLOGIQUE DONC PEUT-ÊTRE UN AVC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Neurologic disorder NOS
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nervous system disorder

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
3 Days		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DONC PEUT-ÊTRE UN AVC

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	CVA
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MA MERE L'A TROUVE INCONSCIENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unconscious
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Loss of consciousness

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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Canada Vigilance AER#:	000945483 (1)	Page#10

Summary (B.5)

Case narrative (B.5.1)

null

Dhpr log details:
Safety Report ID: CA-DHPR-20210412145858_26367
Type of Report: Initiale
HC Ref. No:
Reporter File No.:
Transmission Date: 20210412
First Name: [redacted]
Last Name:
Telephone:
Ext.:
Address:
City:
Province/Territory
Postal Code:
Email address:
Organization:
Reporter Type: Consommateur ou autre non-professionnel de la santé

Patient ID: [redacted]
Age: 89 Année(s)
Sex: Homme
Height: 155 cm
weight: 55 kg
Med History: Vieillesse, historique de parkinson mais à évolution lente (médicaments diminuait de beaucoup symptômes), dépression, problème de prostate
Allergies:

Serious Death: Oui
Date of Death: 2021[redacted]
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome:
Reaction Start Date:
Reaction End Date:
Reaction Description: Mon père a été vacciné pour la Covid[redacted]2021 à 16h30pm. Il est ensuite décédé dans la nuit le [redacted]2021. Aucune autopsie n'a été faite mais selon les ambulanciers ce serait neurologique donc peut-être un AVC. Il n'y a aucun antécédent de crise cardiaque ou AVC dans sa famille. Peut-être n'y a t'il aucun lien mais je voulais soumettre son cas pour recherches.

Suspect Product 1
DIN #/NPN #: A4H1K2
Product Name: Vaccin Pfizer-Biontech
Strength: 0 ml millilitre(s)
Strength other:
Dosage form: 0.3ml
Manufacturer: Pfizer
Lot #: A4H1K2 (?)
Expiry date:
Product start date: 2021[redacted]
Product end date:
Dose:
Frequency:
Route of administration:
Route of administration - Other:
Indication:
Reported to Mfr: Oui
Date reported to Mfr: 20210401
Mfr Reference number:
Drug action taken: Inconnu
Dechallenge:
Rechallenge:

Concomitants: Voici la liste des médicaments qu'il prenait :
- Finasteride 5mg (pour prostate)
- Pantoprazole (40mg) (estomac)
- Auro-Mirtazapi (15mg)
- Apo-Levocarb (25mg-100mg)
- Tamsulosin Cr (0.4mg)
- Teva-Loperamid (2mg) (au besoin si diarrhée)
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Parkinson's disease NOS		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Depression		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Prostatic disorder		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Non-smoker		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Vieillesse, historique de parkinson mais à évolution lente (médicaments diminuait de beaucoup symptômes), dépression, problème de prostate

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) [redacted]	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) [redacted]
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) [redacted]			
Reporter city (A.2.1.2d) [redacted]		Reporter state (A.2.1.2e) [redacted]	
Reporter postcode (A.2.1.2f) [redacted]	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04337405 (5)	Page#1
Canada Vigilance Adverse Reaction Report	**HC Latest Received Date:**	20220606 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021708116(6)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210611 CCYYMMDD	20220602 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021708116

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada BRISTOL-MYERS SQUIBB COMPANY Health Canada BRISTOL-MYERS SQUIBB COMPANY PFIZER INC BRISTOL-MYERS SQUIBB COMPANY PFIZERINC	E2B_04369581 CA-BRISTOL-MYERS SQUIBB COMPAN - BMS-021-125883 CA-HEALTHCANVIG-E2B_04943036 CA-BRISTOL-MYERS SQUIBB COMPANYBMS-2021-062888 CA-PFIZER INC-202101624815 CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2021-064624 CA-PFIZER INC-2021708116

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_04369586

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

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Canada Vigilance AER#:	E2B_04337405 (5)	Page#2

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			102 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Balance impaired NOS
26.0	Confused
26.0	Congestive heart failure
26.0	Difficulty in walking
26.0	Disease recurrence
26.0	Fatigue
26.0	Fluid retention
26.0	General physical health deterioration
26.0	Increased blood pressure
26.0	Pulmonary edema
26.0	Sleepy
26.0	Swelling of feet
26.0	Weight gain

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML
Active Substance names (B.4.k.2.2)	
tozinameran	
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**
Canada	
Holder and authorization/application no. of drug (B.4.k.4)	

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Canada Vigilance AER#:	E2B_04337405 (5)	Page#3

Authorization/Application no.: 02509210
Country of authorization/application: Canada

Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intramuscular	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 9090 Minutes	**Last period (B.4.k.13.2)** 9090 Minutes	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Balance impaired NOS	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Balance impaired NOS	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Confused	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Confused	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Congestive heart failure	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Congestive heart failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Difficulty in walking	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Difficulty in walking	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Disease recurrence	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Disease recurrence	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fatigue	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	General physical health deterioration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	General physical health deterioration	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Increased blood pressure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulmonary edema	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulmonary edema	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sleepy	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sleepy	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swelling of feet	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swelling of feet	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Water retention	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Water retention	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Weight gain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Weight gain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PERINDOPRIL	
Active Substance names (B.4.k.2.2)		
perindopril		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Blood pressure high
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
2017 CCYY		
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METOPROLOL	
Active Substance names (B.4.k.2.2)		
metoprolol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	AFib
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
2017 CCYY		
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) APIXABAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12) 2004 CCYY	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ELIQUIS FILM COATED	
Active Substance names (B.4.k.2.2)		
apixaban		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2.5 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6)		
2.5 mg, twice daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet		
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20170130 CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
1504 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TIMOLOL MALEATE	
Active Substance names (B.4.k.2.2) timolol maleate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12) 20150721 CCYYMMDD	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	OMNARIS	
Active Substance names (B.4.k.2.2)		
ciclesonide		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02303671 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2 Dosage forms,1 every 1 (Days)		
Dosage text (B.4.k.6)		
2 sprays, once daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12) 20170605 CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 1378 Days	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN D3	
Active Substance names (B.4.k.2.2)		
vitamin d3		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02496992 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
2000 IU (International Unit),1 every 1 (Days)		
Dosage text (B.4.k.6)		
2000 iU, once daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12) 20170609 CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 1374 Days	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CALCIUM	
Active Substance names (B.4.k.2.2)		
calcium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
500 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6)		
500 mg, twice daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20170610 CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
1373 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RISEDRONATE	
Active Substance names (B.4.k.2.2)		
risedronate sodium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02370239 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
35 Milligram,1 every 1 (Weeks)		
Dosage text (B.4.k.6)		
35 mg, weekly		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12) 20170609 CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 1374 Days	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACETAMINOPHEN	
Active Substance names (B.4.k.2.2)		
acetaminophen		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
1 to 2 tablets, thrice daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet		
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20200629 CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
258 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	COVERSYL [PERINDOPRIL ARGININE]	
Active Substance names (B.4.k.2.2)		
PERINDOPRIL ARGININE		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
2 mg, once daily		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Tablet		
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
20190311 CCYYMMDD		
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
734 Days		
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FEET SWELLING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Swelling of feet		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Peripheral swelling		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

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9090 Minutes 1504 Days 1378 Days 1373 Days 1374 Days 258 Days 734 Days	9090 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FEET SWELLING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Disease recurrence
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Disease recurrence

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
9090 Minutes	9090 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LACK OF BALANCE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Balance impaired NOS
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Balance disorder

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
9090 Minutes	9090 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SLEEPIER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sleepy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Somnolence

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
9090 Minutes	9090 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MORE DIFFICULTIES TO WALK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Difficulty in walking
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Gait disturbance

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
17730 Minutes	17730 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CONFUSED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Confused		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Confusional state		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
17730 Minutes	17730 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CONGESTIVE HEART FAILURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Congestive heart failure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Cardiac failure congestive		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WATER ON HIS LUNG AND IN HIS BODY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pulmonary edema		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Pulmonary oedema		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WATER ON HIS LUNG AND IN HIS BODY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Water retention		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Fluid retention		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD PRESSURE HAS BEEN ELEVATED INTO THE 160S

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Increased blood pressure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Blood pressure increased		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

GAINED SOME WEIGHT, APPROXIMATELY 10 POUNDS IN ABOUT ONE WEEK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Weight gain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Weight increased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WORSENING FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fatigue		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Fatigue		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEALTH DROPPED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	General physical health deterioration		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	General physical health deterioration		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Swelling of legs		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Peripheral swelling		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	

Summary (B.5)

Case narrative (B.5.1)

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This is a spontaneous report received from contactable consumer (patient's daughter) and physician.

A 102-year-old male patient received BNT162b2 (BNT162B2), on [redacted]2021 at 16:30 as dose 1, single (Batch/Lot number: unknown) at the age of 102 years intramuscular, in left arm for COVID-19 immunisation. The patient's relevant medical history included: "Blood pressure high", start date: 2017 (ongoing); "AFib heart", start date: 2017 (ongoing); "Feet swollen" (unspecified if ongoing), notes: For few years but they were able to manage it; "Glaucoma" (unspecified if ongoing); "Suspect pneumonia", start date: May2017 (unspecified if ongoing), notes: Chest X-ray was negative; "Weight loss", start date: May2017 (unspecified if ongoing); "Osteoporosis", start date: Jun2017 (unspecified if ongoing), notes: on treatment; "Cholesterol", start date: 1985 (unspecified if ongoing); "COVID" (unspecified if ongoing), notes: March 7 (unspecified year); "Vein occlusion", start date: Jul2015 (unspecified if ongoing); "Peripheral arterial disease" (unspecified if ongoing), notes: PAD; "Allergies are to shellfish" (unspecified if ongoing); "Non-smoker" (unspecified if ongoing); "Seldom uses EtOH" (unspecified if ongoing); "Foley catheter" (unspecified if ongoing); "Palpitation" (unspecified if ongoing). Concomitant medications included: PERINDOPRIL oral taken for hypertension, start date: 2017 (ongoing); METOPROLOL oral taken for atrial fibrillation, start date: 2017 (ongoing); APIXABAN oral, start date: 2004 (ongoing); ELIQUIS, start date: 30Jan2017; TIMOPTIC, start date: 21Jul2015; OMNARIS, start date: 05Jun2017; VITAMIN D3, start date: 09Jun2017; CALCIUM, start date: 10Jun2017; RISEDRONATE, start date: 09Jun2017; ACETAMINOPHEN, start date: 29Jun2020; COVERSYL [PERINDOPRIL ARGININE], start date: 11Mar2019. Past drug history included: Norvasc for Hypertension, reaction(s): "Leg swelling", notes: Tablet, Strength: 5 mg. Vaccination history included: Fluviral (Old formulation), administration date: 01Nov2017, when the patient was 98-year-old, for Immunization; Zostavax, administration date: 01Nov2017, when the patient was 98-year-old, for Immunization; td, administration date: 21Jul2015, when the patient was 96-year-old, for Immunization; Fluzone high dose, administration date: 13Nov2018, when the patient was 99-year-old, for Immunization; Pneumo 23, administration date: Jul2012, when the patient was 93 years old, for Immunization. The patient received his first Pfizer vaccine on [redacted]2021. On [redacted]021 (a week after receiving the vaccine), the patient experienced feet swelling (swollen), lack of balance, and became sleepier which resulted in death and required emergency room visit. The swollen feet were something the patient had for few years, but they were able to manage it. He was able to walk by himself, etc. He lived with his daughter. On [redacted]2021, the patient's called his doctor to have him checked as he had swollen feet and was furniture surfing as he had like a lack of balance. The doctor said that he will see him [redacted]2021. On [redacted]021, his father had more and more difficulties to walk and was sleepier and a bit confused too. So, the patient's daughter called the ambulance. At the hospital, the doctor said that the patient has congestive heart failure, he had water on his lung and in his body. He was given furosemide (LASIX) from [redacted]021, and dose was increased from [redacted]2021; metoprolol tartrate 25 mg 1 tablet 2 times daily from [redacted]2021 and amlodipine 5 mg 1 tablet once daily from [redacted]2021 and hold when blood pressure was less than 130 mmHg. He stayed 1 week at the hospital (from [redacted]021 to [redacted]2021) and finally passed away on [redacted]2021. As of [redacted]021, the patient's blood pressure has been elevated into the 160s [redacted]2021) and he has had some edema and also has gained some weight, approximately 10 pounds in about one week and has endorsed in the past couple of days some worsening fatigue, prompting the patient to be brought into the emergency room evening after feeling greatly fatigued and noticing something worst [redacted]021). The patient's daughter was under the impression that after the vaccine, his health dropped, and pushed him over the edge. The patient was hospitalized for all events from [redacted]2021 to [redacted]2021. The outcome of the events was fatal. The patient died on [redacted]2021. It was not reported if an autopsy was performed.

Follow-up [redacted]021): New information received from the same contactable consumer (patient's daughter) includes additional medical history (glaucoma, suspect pneumonia, weight loss, osteoporosis, blood cholesterol abnormal, vein occlusion, peripheral arterial disease (PAD), allergy to shellfish, non-smoker and alcohol use), historical vaccine, additional concomitant medications (ELIQUIS, TIMOPTIC-XE, OMNARIS, VITAMIN D3, calcium, risedronate from 09Jun2017, acetaminophen, COVERSY and ''dobetasol''), past drug history, treatments received and subject's clinical course.

Follow-up (02Jul2021): This is a follow-up spontaneous report from a contactable physician, based on information received by Pfizer from Bristol-Myers Squibb (Manufacturer control number: CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-064624).

This case was received via Pfizer Inc (Reference number: 2021764189) on 25Jun2021 and was forwarded to BMS on 25Jun2021. This spontaneous case was reported by a physician and describes the occurrence of DEATH (Deceased) in 102-year-old male patient who received apixaban (Eliquis) tablet for Cerebrovascular accident prophylaxis. CO-SUSPECT PRODUCTS included tozinameran (Pfizer Biontech Covid-19 Vaccine) for an unknown indication. The patient did not receive any prior vaccination and had no family history. The patient's past medical history included "CholE" (1985). The patient's past medical history included Allergy (Norvasc 5 mg Tablet: leg swelling at the age of 98 and shellfish), Nonsmoker, Alcohol use (Seldom uses ETOH), Palpitation, Hypertension, Central retinal vein occlusion (Left - Occurred in [redacted] June) and Foley catheter. On 30-Jan-2017, the patient started Eliquis (Oral), 2.5 milligram twice a day. In [redacted]2021, the patient started Pfizer Biontech Covid-19 Vaccine (unknown route). DEATH occurred in [redacted]2021. The patient died in [redacted] 2021. The cause of death was not reported. It is unknown if an autopsy was performed. For Eliquis (Oral), the reporter did not provide any causality assessments. This case was linked to CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-062888 (E2B Linked Report).

BMS Medical evaluation comment: This patient had died due to unknown reason after apixaban therapy. Based on the limited information regarding medical history, autopsy reports, laboratory reports, treatment details, it cannot be ascertained that the suspect drug contributed to the reported event.

Information about lot/batch number cannot be obtained. No further information expected.

Follow-up (27Aug2021): This follow-up is being submitted to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Follow-up (27May2022): This is a spontaneous follow-up report received from a contactable physician. Other Case identifier(s): CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-064624 (BRISTOL-MYERS SQUIBB COMPANY).

Supplemental information was received on 19-May-2022 from a Physician which included the following: Past therapy included Pneumo 23 for immunization. Concomitant medications included Metoprolol, Perindopril and Vitamin D3.

Follow-up (02Jun022): This is a follow-up report combining information from duplicate reports 2021708116 and 202101624815. The current and all subsequent follow-up information will be reported under manufacturer report number 2021708116. Updated information: narrative information.

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This patient died after receiving apixaban therapy. Patient also got vaccinated for COVID- 19. Based on the limited information available regarding the cause of death and autopsy details, it cannot be ascertained with the reasonable possibility that the suspect could have caused the event.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
201705 CCYYMM	Chest X-ray	Negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
202[redacted] CCYYMM	Blood pressure	160s	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMM	Weight	Gained approximately 10	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
lbs			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Blood pressure high	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2017 CCYY	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	AFib	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
2017 CCYY	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Swelling of feet	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
For few years but they were able to manage it		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Glaucoma	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Pneumonia

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
201705 CCYYMM		

Comments (B.1.7.1g)
Chest X-ray was negative

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Weight loss

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
201705 CCYYMM		

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Osteoporosis

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
201706 CCYYMM		

Comments (B.1.7.1g)
on treatment

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Blood cholesterol abnormal

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
1985 CCYY		

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	COVID-19

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)
March 7 (unspecified year)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Venous occlusion

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
201507 CCYYMM		

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Peripheral arterial disease

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)
PAD

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Shellfish allergy

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Non-smoker

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

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Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Alcohol use	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Foley catheter	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Palpitation	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Disease recurrence	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Pulmonary edema	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Fluid retention	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Swelling of feet	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name** (B.1.7.1a.2)	
26.0	Increased blood pressure	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Weight gain	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Balance impaired NOS	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Sleepy	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Difficulty in walking	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	General physical health deterioration	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fatigue	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Confused	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Congestive heart failure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)
FLUVIRAL [INFLUENZA VACCINE INACT SPLIT 3V]

Start date (B.1.8c)	End date (B.1.8e)
20171101 CCYYMMDD	20171101 CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) Immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Drug name (B.1.8a)
FLUZONE HIGH DOSE

Start date (B.1.8c)	End date (B.1.8e)
20181113 CCYYMMDD	20181113 CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) Immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Drug name (B.1.8a)
NORVASC

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) Hypertension
Reaction MedDRA version (B.1.8g.1) v.26.0	**Reaction** (B.1.8g.2) Swelling of legs

Drug name (B.1.8a)
PNEUMO 23

Start date (B.1.8c)	End date (B.1.8e)
20120701 CCYYMMDD	20120701 CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) Immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Drug name (B.1.8a)
TD

Start date (B.1.8c)	End date (B.1.8e)
20150721 CCYYMMDD	20150721 CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) Immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Drug name (B.1.8a)
ZOSTAVAX

Start date (B.1.8c)	End date (B.1.8e)
20171101 CCYYMMDD	20171101 CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) Immunization
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

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Parent (B.1.10)			
Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)		
MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)	
Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04337405 (5)	Page#27

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3)	**Qualification** (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3)	**Qualification** (A.2.1.4)	
	Canada	Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		**Title** (A.3.1.3b)
Given name (A.3.1.3c)	**Middle name** (A.3.1.3d)	**Family name** (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		**State** (A.3.1.4c)
Postcode (A.3.1.4d)		**Country code** (A.3.1.4e)
Tel No. (A.3.1.4f)		**Fax no.** (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04347292 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211018 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A567443()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210624 CCYYMMDD	20211011 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A567443

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA MAH AZPROD0000	E2B_04347292 [redacted] 2021A567443 CA-AstraZeneca-2021A567443

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Clot blood	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
Company		Yes

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Canada Vigilance AER#:	E2B_04347292 (1)	Page#3

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RARE BLOOD CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via a consumer concerning a patient.

No medical history and no concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5 ML (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route and experienced rare blood clots (preferred term: Thrombosis) and thrombosis (preferred term: Thrombosis).

The action taken for received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5 ML was not applicable. The patient died from the event of rare blood clots and thrombosis.

It is not known whether an autopsy was performed. The cause of death was rare blood clots and thrombosis.

The events experienced rare blood clots and thrombosis were considered serious (Death) by MC since the reporter provided a fatal outcome.

The company physician considered the event rare blood clots related to treatment with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5 ML.

Summary of follow-up information received by AstraZeneca 11-oct-2021: Regulatory authority is added in the reporter tab and new event THROMBOSIS is added in the event and death tab. Corrected Report 14-Oct-2021: The batch number was removed.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.CAUSE OF DEATH: RARE BLOOD CLOTS CAUSE OF DEATH: THROMBOSIS REPORTER'S COMMENTS: Adverse Reaction Report Number: E2B_04347292
Latest AER Version Number: 0
Initial Received Date: 29Jun2021
Latest Received date: 29Jun2021
Source of Report: MAH
Market Authorization Holder AER Number: 2021A567443
Type of Report: Spontaneous
Reporter type: Consumer/other non health professional
Serious report? Serious
Death: Yes
Life Threatening: No
Disability: No
Hospitalization: No
Congenital Anomaly: No
Other Medically Important Conditions: No
Patient Information
Age: -
Gender: -
Height: -
Weight: -
Report Outcome: Fatal
Link Duplicate Report Information
Record Type: No duplicate or linked report.
Link AER*** Number
Product Information
Product Description: ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML
Health Product Role: Suspect
Dosage Form: -
Route of Administration: Intramuscular
Dose: -
Frequency: -
Therapy Duration: -
Indication(s) : Product used for unknown indication
Adverse Reaction Term Information
Adverse Reaction Term(s): Thrombosis
MedDRA Version: v.24.0
Reaction Duration: -
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

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Adverse Reaction Report Number: E2B_04347292
Latest AER Version Number: 0
Initial Received Date: 29Jun2021
Latest Received date: 29Jun2021
Source of Report: MAH
Market Authorization Holder AER Number: 2021A567443
Type of Report: Spontaneous
Reporter type: Consumer/other non health professional
Serious report? Serious
Death: Yes
Life Threatening: No
Disability: No
Hospitalization: No
Congenital Anomaly: No
Other Medically Important Conditions: No
Patient Information
Age: -
Gen...

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal events of thrombosis (reported as RARE BLOOD CLOTS) and thrombosis (reported as THROMBOSIS) are not listed in the company core data sheet of AZD1222. The events could be in association with each other. Due to limited information on further clarification of the events, circumstances leading to the events, administration date of AZD1222, onset date of the events, baseline health condition before vaccination especially cardiovascular status, clinical course, treatment details, underlying comorbidities, past and current medical history, family history, concomitant medications, risk factors (smoking, obesity, sedentary lifestyle, diabetes, dyslipidemia, coagulation disorders), date of death, autopsy report, etiologic and diagnostic workup (detailed history, clinical examination, complete blood count, D dimer levels, coagulation profile, relevant imaging studies), the evaluation did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Canada Vigilance AER#:	E2B_04347292 (1)	Page#8

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

ATIA - 19(1)

Canada Vigilance AER#:	E2B_04369581 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220527 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-064624(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220519 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-064624

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) BRISTOL-MYERS SQUIBB COMPANY	**Duplicate Case identifiers (A.1.11.2)** CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-064624

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04369586, (2) E2B_04933375, (2) E2B_04369586, (2) E2B_04369586

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - BRISTOL-MYERS SQUIBB

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)** Elderly		**Onset Age (B.1.2.2)** 102 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMM	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	APIXABAN	
Active Substance names (B.4.k.2.2)		
apixaban		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2.5 Milligram,1 every .5 (Days)		
Dosage text (B.4.k.6)		
2.5 milligram, bid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Cerebrovascular accident prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20170130 CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
4 Years		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable	Unknown	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
26.0	Death	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Global Introspection	No Information

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	TOZINAMERAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	Unknown	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202106 CCYYMM		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
1 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable	Unknown	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
26.0	Death	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Company	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Reporter	Global Introspection	No Information

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METOPROLOL	
Active Substance names (B.4.k.2.2)		
metoprolol		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
12.5 Milligram,1 every .5 (Days)		
Dosage text (B.4.k.6)		
12.5 milligram, bid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PERINDOPRIL	
Active Substance names (B.4.k.2.2)		
perindopril		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
2 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
2 milligram, daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN D3	
Active Substance names (B.4.k.2.2)		
vitamin d3		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02496992 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK, daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DECEASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Death		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Death		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
4 Years 1 Days		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This case was received via Pfizer Inc (Reference number: 2021764189) on [redacted]2021 and was forwarded to BMS on [redacted]2021.
This spontaneous case was reported by a physician and describes the occurrence of DEATH (Deceased) in 102-year-old male patient who received apixaban (Eliquis) tablet for Cerebrovascular accident prophylaxis.

CO-SUSPECT PRODUCTS included tozinameran (Pfizer Biontech Covid-19 Vaccine) for an unknown indication.

The patient did not receive any prior vaccination and had no family history.

The patient's past medical history included "CholE" (1985).
The patient's past medical history included Allergy (Norvasc 5 mg Tablet: leg swelling at the age of 98 and shellfish), Nonsmoker, Alcohol use (Seldom uses ETOH), Palpitation, Hypertension, Central retinal vein occlusion (Left - Occurred in 15th June) and Foley catheter.

On 30-Jan-2017, the patient started Eliquis (Oral), 2.5 milligram twice a day. In [redacted]2021, the patient started Pfizer Biontech Covid-19 Vaccine (unknown route). DEATH occurred in [redacted]2021. The patient died in [redacted]2021. The cause of death was not reported. It is unknown if an autopsy was performed.

For Eliquis(Oral), the reporter did not provide any causality assessments.

This case was linked to CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-062888 (E2B Linked Report).

BMS Medical evaluation comment: This patient had died due to unknown reason after apixaban therapy. Based on the limited information regarding medical history, autopsy reports, laboratory reports, treatment details, it cannot be ascertained that the suspect drug contributed to the reported event.

Supplemental information was received on 19-May-2022 from a Physician which included the following:

Past therapy included Pneumo 23 for immunization. Concomitant medications included Metoprolol, Perindopril and Vitamin D3.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This patient died after receiving apixaban therapy. Patient also got vaccinated for COVID- 19. Based on the limited information available regarding the cause of death and autopsy details, it cannot be ascertained with the reasonable possibility that the suspect could have caused the event.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug hypersensitivity	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Unknown	

Comments (B.1.7.1g)

Norvasc 5 mg Tablet: leg swelling at the age of 98 and

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Alcohol use	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Unknown	

Comments (B.1.7.1g)

Seldom uses ETOH

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Retinal vein occlusion	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		
Left - Occurred in [redacted]		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Palpitations	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Non-tobacco user	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Bladder catheterisation	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	No	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Atrial fibrillation	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
2017 CCYY	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Food allergy	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

The patient did not receive any prior vaccination and had no family history.The patient's past medical history included "CholE" (1985)

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Past drug therapy (B.1.8)

Drug name (B.1.8a) PNEUMO 23	
Start date (B.1.8c) 20120721 CCYYMMDD	**End date** (B.1.8e) CCYYMMDD
Indication MedDRA version (B.1.8f.1) 26.0	**Indication** (B.1.8f.2) Immunisation
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	**DOB of Parent** (B.1.10.2.1)	**Age** (B.1.10.2.2)	**LMP date** (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	**Medical history** (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b)	**Reporter middle name** (A.2.1.1c)	**Reporter family name** (A.2.1.1d)
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04392144 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211123 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A603088()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210706 CCYYMMDD	20211121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A603088

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	E2B_04392144 [redacted] CA-AstraZeneca-2021A603088

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (2) , (2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			52 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer. The report concerns a female patient of Unknown ethnic origin (age 52 years).

The patients past and current medical history were not reported.

On an unknown date the patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. (covid-19 vaccine nrvv ad (chadox1 ncov-19)) once/single administration, via intramuscular route, for product use for unknown indication.

On an unknown date, the patient experienced thrombosis (preferred term: Thrombosis). On an unknown date, the patient experienced blood clots (preferred term: Thrombosis).

It was not applicable if any action was taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. (covid-19 vaccine nrvv ad (chadox1 ncov-19)).

The patient died from the event of thrombosis and blood clots on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was blood clots and thrombosis.

The following events were considered serious due to death: thrombosis and blood clots. The following events were considered serious due to important medical event: thrombosis.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship was unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine was an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca/MedImmune on 21-Nov-2021 A spontaneous report received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer. Added regulatory authority in reporter tab, added indication for suspect, removed the lot no unknown, added strength and frequency, added event thrombosis. Changed the action taken from unknown to not applicable as it was a fatal case. Added thrombosis in death tab and updated narrative.CAUSE OF DEATH: BLOOD CLOTS CAUSE OF DEATH: THROMBOSIS
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal event of Thrombosis (reported as BLOOD CLOTS and THROMBOSIS) is not listed in company core data sheet of AZD 1222. Due to limited information on health status of the patient before vaccination, exact date of event onset and fatal outcome, date of vaccination, localization of thrombosis, exact circumstances leading to the event, concurrent conditions (chronic obstructive pulmonary disease, congestive heart failure, atherosclerosis), concomitant medications, medical history (cardiovascular disease, deep venous thrombosis, traumatic injury, neoplastic disease, thrombophilia), family history, risk factors (stress, smoking, diabetes, hypertension, arrythmia, hypercholesterolemia), detailed etiological and diagnostic workup (complete physical exam, complete blood profile including platelet count, fibrin D dimer test and complete coagulation panel, cardiac assessment, echocardiogram, relevant computerized tomography or magnetic resonance imaging, doppler ultrasound, and complete autopsyy report), the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Clot blood		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)		
26.0	Thrombosis		
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)	
Comments (B.1.7.1g)			

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) PRIVACY	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) CANADIAN HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) PRIVACY	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4)	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b) UNKNOWN	Reporter middle name (A.2.1.1c) UNKNOWN	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		Reporter state (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4)	
Literature reference(s) (A.2.2)			

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Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	
Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) Confidential
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211018 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021845865(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210706 CCYYMMDD	20211012 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) CA-PFIZER INC-2021845865

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada PFIZERINC	000943098 CA-PFIZER INC-2021845865

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			85 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Disease progression
26.0	Dizziness
26.0	Fall
26.0	Malaise
26.0	Prostate cancer

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Disease progression	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dizziness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Malaise	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Prostate cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ELIGARD	
Active Substance names (B.4.k.2.2)		
leuprolide acetate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
30 Milligram		
Dosage text (B.4.k.6)		
30 mg 1 every 4 Months		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Subcutaneous	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Prostate cancer
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIZZINESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dizziness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Dizziness		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

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FALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fall		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fall		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MALAISE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Malaise		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Malaise		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DISEASE PROGRESSION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Disease progression		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Disease progression		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PROSTATE CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Prostate cancer		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Prostate cancer		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a Non-Interventional Study report from a contactable Consumer and a contactable Other Health Professional. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number 000943098. This information was initially reported to Health Canada on 19Mar2021 from an unknown Market Authorization Holder AER# unspecified.

An 85-year-old male patient received bnt162b2 (reported as COVID-19 VACCINE, Batch/Lot number was not reported), intramuscularly on an unspecified date as single dose for covid-19 immunisation; leuprorelin acetate (ELIGARD, 30 mg), subcutaneously from an unspecified date to an unspecified date, then from an unspecified date to an unspecified date, both at 30 mg 1 every 4 Months for prostate cancer. The patient's medical history and concomitant medications were not reported. The patient experienced dizziness, fall, malaise, disease progression and prostate cancer on an unspecified date. The events were reported as serious, serious criteria was reported as death. The action taken in response to the events for leuprorelin acetate was unknown. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Follow-up (12Oct2021): This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report number 000943098. This information was initially reported to Health Canada between 19Mar2021 and 03Jun2021 from an unknown Market Authorization Holder. New information received from a contactable Other Health Professional includes: new events disease progression and prostate cancer were added.

The reporter's assessment of the causal relationship of the events with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.
COVID-19 Vaccine - Manufacturer Unknown approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on temporal association, the causal relationship between bnt162b2 and the events dizziness and malaise cannot be excluded. The event fall is not considered to be directly related to the suspect drug; it is most likely due to another event or an external factor. The causal relationship of prostate cancer and disease progression is consider unrelated ; the status of prostate cancer, patient overall health condition as of vaccination day, and circumstances surrounding death were not reported. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Disease progression	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Prostate cancer	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dizziness	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fall	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Malaise	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04406581 (1)	Page#8

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
	Other studies

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04410794 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210713 CCYYMMDD
	HC Initial Received Date:	20210713 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A615259()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210709 CCYYMMDD	20210709 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A615259

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
MC Canada AZPROD0000	[redacted] CA-AstraZeneca-2021A615259

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death

MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from a consumer. The report concerns a male patient (age not provided) of Unknown ethnic origin.

No medical history was reported.

No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml. (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN) 0.5 ml, via intramuscular route, on an unknown date.

The patient died (MedDRA PT: Death) on an unspecified date.

It is not known whether an autopsy was performed. The cause of death was died.

Additional description of the event(s) was as follows: consumer knows only of women who got blood clots but she actually knows of 3 men who died.

The event was considered serious (death).

CAUSE OF DEATH: DIED
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

This case report concerns a male patient with reported fatal outcome (PT: death) in association with AZD 1222. Cause of death was reported as died. Due to limited information regarding patient´s age, date of vaccination, date of death, baseline health condition before vaccination, relevant patient´s and family history, concurrent diseases, concomitant medications, risk factors and in the absence of an autopsy report, the evaluation did not find evidence to suggest a causal relationship between the event and AZD 1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Death	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)		End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)		Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)		Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)		Medical history (B.1.10.7.1a.2)
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)		
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04427654 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211124 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A619614()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210712 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211121 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A619614

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_04427654 [redacted] CA-AstraZeneca-2021A619614

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Clot blood
26.0	Thrombosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
.5 ml		
Dosage text (B.4.k.6)		
Dose Unknown0.5mL ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BLOOD CLOTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Clot blood		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via health professional concerning a patient of unknown gender (age not provided) of Unknown ethnic origin.

No medical history was reported. No concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) Dose Unknown, 0.5 ml once/single administration, via intramuscular route, for product used for unknown indication on an unknown date. On an unknown date, the patient experienced blood clots (preferred term: Thrombosis), thrombosis (preferred term: Thrombosis).

Action taken with suspect Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable. The patient died from the event of blood clots and thrombosis on an unspecified date.

The cause of death was blood clots and thrombosis. It was not known whether an autopsy was performed.

The events blood clots and thrombosis were considered serious (death) by AstraZeneca (MC).

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca 21-NOV-2021 received via sapphire: A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via health professional, new reporter regulatory authority added, last name for reporter type other masked, indication and frequency for suspect added, new event thrombosis added, narrative updated.
CAUSE OF DEATH: BLOOD CLOTS CAUSE OF DEATH: THROMBOSIS BLOOD CLOTS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes THROMBOSIS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal event of Thrombosis with fatal outcome (death) is not listed in the company core data sheet of AZD1222. Due to limited information on the baseline health characteristics of patient before vaccination, including patient demographic details and date of vaccination, and further circumstances leading to the event, event details including date of onset, relevant medical and family history, concurrent diseases and concomitant medications, risk factors, aetiological and complete diagnostic workup, and autopsy report, the evaluation did not find evidence to suggest a causal relationship between event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Clot blood	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04430265 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211124 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A623920()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210713 CCYYMMDD	20211121 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	**Company number (A.1.10.2)** CA-AstraZeneca-2021A623920

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	E2B_04430265 [redacted] CA-AstraZeneca-2021A623920

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			54 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04430265 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral venous thrombosis
26.0	Fatigue extreme
26.0	Headache
26.0	Heparin-induced thrombocytopenia
26.0	Platelet count decreased
26.0	Subdural bleeding
26.0	Thrombocytopenia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 1		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PLATELET COUNT DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Platelet count decreased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Platelet count decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBRAL VENOUS THROMBOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral venous thrombosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cerebral venous thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			10 Days
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			10 Days
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUBDURAL BLEEDING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Subdural bleeding		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Subdural haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEPARIN INDUCED THROMBOCYTOPENIA TEST POSITIVE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heparin-induced thrombocytopenia test positive		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Heparin-induced thrombocytopenia test positive		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)

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No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

EXTREME FATIGUE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Fatigue extreme
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Fatigue

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via consumer. The report concerned a female patient of Unknown ethnic origin (age 54 years).

No medical history was reported and no concomitant products were reported.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)),Dose 1 via intramuscular route, for covid 19 immunisation on [redacted]2021. On an unknown date, the patient experienced platelet count decreased (preferred term: Platelet count decreased). On an unknown date, the patient experienced cerebral venous thrombosis (preferred term: Cerebral venous thrombosis). On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia). On an unknown date, the patient experienced subdural bleeding (preferred term: Subdural haemorrhage). On an unknown date, the patient experienced headaches (preferred term: Headache). On an unknown date, the patient experienced heparin induced thrombocytopenia test positive (preferred term: Heparin-induced thrombocytopenia test positive). On an unknown date, the patient experienced extreme fatigue (preferred term: Fatigue).Ten days post vaccination, patient presented with headaches and extreme fatigue. Hospital detected subdural bleeding. Patient was transferred to Neurology. Laboratory values were available. Scan was done showed deep cerebral vein thrombosis with several clots. Platelet count was done were at 10.Anti PF4 (ELISA) was done result was positive it deceased on [redacted] 2021.

The action taken with Covid-19 Vaccine Astrazeneca was not applicable. Patient received immunoglobulin. The outcome from the event of platelet count decreased, cerebral venous thrombosis, thrombocytopenia, subdural bleeding, headaches, heparin induced thrombocytopenia test positive and extreme fatigue was fatal.

The patient died on [redacted]2021. The cause of death was platelet count decreased, cerebral venous thrombosis, thrombocytopenia, subdural bleeding, headaches, heparin induced thrombocytopenia test positive and extreme fatigue. It was not known whether an autopsy was performed.

The events were considered serious (death, hospitalised and important medical event).

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca on 21-NOV-2021 via consumer from spontaneous report. Regulatory Authority was updated as first reporter with reporter?s Id E2B_04430265. Indication was updated as covid 19 immunisation. As per company physician event of anti pf4 elisa positive was updated as heparin induced thrombocytopenia test positive and event platelets were at 10 was updated as platelet count decreased and all the events seriousness criteria was updated as death, hospitalised and important medical event.CAUSE OF DEATH: PLATELET COUNT DECREASED CAUSE OF DEATH: CEREBRAL VENOUS THROMBOSIS CAUSE OF DEATH: THROMBOCYTOPENIA CAUSE OF DEATH: SUBDURAL BLEEDING CAUSE OF DEATH: HEADACHES CAUSE OF DEATH: HEPARIN INDUCED THROMBOCYTOPENIA TEST POSITIVE CAUSE OF DEATH: EXTREME FATIGUE Unstructured Test Result (Test #1) : Scan showed deep cerebral vein thrombosis with several clots Lab Test #1 : 10061498 Lab Test #2 : 10035525 Lab Test #3 : 10059717
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal events of Subdural hemorrhage and Heparin-induced thrombocytopenia test positive are not listed in the company core sheet for AZD1222. Fatigue and Headache are listed are listed in company core data sheet of AZD1222. However, since the event were reported with a fatal outcome, they are considered unlisted. Thrombosis (Preferred term: Cerebral venous thrombosis) in combination with thrombocytopenia (Preferred term: Thrombocytopenia and Preferred term: Platelet count decreased) is listed in the company core data sheet of AZD1222. However, since the events were reported with a fatal outcome, it is considered unlisted. The events could be in association with each other. Due to limited information on the further clarification of the events, circumstances leading to the events, patients baseline health status before vaccination, relevant medical history (deep venous thrombosis, traumatic injury, neoplastic disease, thrombophilia), concurrent diseases (hypertension, diabetes mellituss, infections, coagulation disorders), concomitant medications, risk factors (prolonged immobilization, smoking, obesity), etiological and complete diagnostic work-up (full diagnostic laboratory panel, complete physical examination, cardiology examination, brain imaging, other relevant imaging studies) and complete autopsy report, the evaluation did not find evidence to suggest a causal relationship between the events and the vaccine AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)	
	ELISA		POSITIVE	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**		**More info (B.3.1.3)**
				No

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)	
	Platelet count		10	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**		**More info (B.3.1.3)**
				No

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)	
	Scan		Scan showed deep cerebral vein thrombosis with ...	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**		**More info (B.3.1.3)**
				No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Platelet count decreased	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral venous thrombosis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Subdural bleeding	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Headache	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Heparin-induced thrombocytopenia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1) 26.0	**Episode name** (B.1.7.1a.2) Fatigue extreme	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date** (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	**DOB of Parent** (B.1.10.2.1)	**Age** (B.1.10.2.2)	**LMP date** (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	**Medical history** (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) PRIVACY	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) CANADIAN HEALTH AUTHORITY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	

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Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) PRIVACY	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4)	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b) PRIVACY	**Reporter middle name** (A.2.1.1c) UNKNOWN	**Reporter family name** (A.2.1.1d) UNKNOWN
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c) UNKNOWN			
Reporter city (A.2.1.2d) UNKNOWN		**Reporter state** (A.2.1.2e) UNKNOWN	
Reporter postcode (A.2.1.2f) UNKNOWN	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4)	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		**Project No**	
Sponsor Study no. (A.2.3.2)		**Observed study type** (A.2.3.3)	

Reporter title (A.2.1.1a)	**Reporter given name** (A.2.1.1b)	**Reporter middle name** (A.2.1.1c)	**Reporter family name** (A.2.1.1d) Confidential
Reporter organization (A.2.1.2a)		**Reporter department** (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		**Reporter state** (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	**Reporter country** (A.2.1.3) Canada	**Qualification** (A.2.1.4) Consumer/other non health professional	

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Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04430487 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20211125 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A623885()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210713 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211121 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A623885

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** E2B_04430487 [redacted] CA-AstraZeneca-2021A623885

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2) , (2)

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Afebrile seizure
26.0	Consciousness loss
26.0	Heparin-induced thrombocytopenia test positive
26.0	Immune thrombocytopenia
26.0	Intracerebral hemorrhage
26.0	Platelet count decreased
26.0	Thrombocytopenia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Canada Vigilance AER#:	E2B_04430487 (1)	Page#3

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	MT0055	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose 1-Dose number: 1		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

AFEBRILE SEIZURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Afebrile seizure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Seizure		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PLATELET COUNT DECREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Platelet count decreased		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Platelet count decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VIIT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Immune thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Immune thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTRACEREBRAL HEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Intracerebral hemorrhage		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Cerebral haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
No			
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CONSCIOUSNESS LOSS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Consciousness loss
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)
26.0	Loss of consciousness

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
No				
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HIT ASSAY RESULT POSITIVE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heparin-induced thrombocytopenia test positive		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Heparin-induced thrombocytopenia test positive		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via Consumer concerning a male patient (age not provided) of Unknown ethnic origin.

The patient's past and current medical history included hypertension (dates not reported) and gastroesophageal reflux disease (dates not reported). No concomitant products were reported.

The patient received AstraZeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number MT0055), via intramuscular route, for product used for unknown indication on 16-APR-2021. On an unknown date, the patient experienced afebrile seizure (preferred term: Seizure). On an unknown date, the patient experienced thrombocytopenia (preferred term: Thrombocytopenia). On an unknown date, the patient experienced platelet count decreased (preferred term: Platelet count decreased). On an unknown date, the patient experienced viit (preferred term: Immune thrombocytopenia). On an unknown date, the patient experienced intracerebral hemorrhage (preferred term: Cerebral haemorrhage). On an unknown date, the patient experienced consciousness loss (preferred term: Loss of consciousness). On an unknown date, the patient experienced hit assay result positive (preferred term: Heparin-induced thrombocytopenia test positive). Laboratory data was available. on an unknown date tested HIT Assay and the result was positive.

Action taken for AstraZeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable. The patient died from the event of afebrile seizure, thrombocytopenia, platelet count decreased, viit, intracerebral hemorrhage, consciousness loss and hit assay result positive on [redacted]2021.

It is not known whether an autopsy was performed. The cause of death was afebrile seizure, thrombocytopenia, platelet count decreased, viit, intracerebral hemorrhage, consciousness loss and hit assay result positive.

The following events were considered serious due to death: afebrile seizure, thrombocytopenia, platelet count decreased, viit, intracerebral hemorrhage, consciousness loss and hit assay result positive. The following events were considered serious due to hospitalized: afebrile seizure, thrombocytopenia, platelet count decreased, viit, intracerebral hemorrhage, consciousness loss and hit assay result positive. The following events were considered serious due to important medical event: afebrile seizure, thrombocytopenia, platelet count decreased, viit, intracerebral hemorrhage, consciousness loss and hit assay result positive.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca 21-NOV-2021: A spontaneous report has been received from the regulatory authority in Canada via consumer. Added Regulatory Authority as a reporter, event viit was added. Event seriousness criteria was updated. Minor correction 25-NOV-2021: Platelet count decreased was deleted from the lab field as the values are not available.CAUSE OF DEATH: AFEBRILE SEIZURE CAUSE OF DEATH: THROMBOCYTOPENIA CAUSE OF DEATH: PLATELET COUNT DECREASED CAUSE OF DEATH: VIIT CAUSE OF DEATH: INTRACEREBRAL HEMORRHAGE CAUSE OF DEATH: CONSCIOUSNESS LOSS CAUSE OF DEATH: HIT ASSAY RESULT POSITIVE Lab Test #1 : 10050829
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal events of seizure, cerebral hemorrhage, platelet count decreased, Immune thrombocytopenia, loss of consciousness, and heparin-induced thrombocytopenia test positive are not listed in company core data sheet of AZD 1222. Thrombocytopenia is listed in the company core data sheet of AZD1222. However, since the event was reported with a fatal outcome, it is considered unlisted. Heparin-induced thrombocytopenia test positive may be in association with thrombocytopenia. Underlying, hypertension may be a contributor risk factor to the events seizure, cerebral hemorrhage, and loss of consciousness. Due to limited information regarding baseline health conditions before vaccination, past medical history of seizure, family history of epilepsy, concurrent conditions (such as intracranial tumor, vascular disorders, metabolic or infectious diseases, head trauma, diabetes mellitus, leukemia) clinical course, etiological and diagnostic work up (complete physical exam including neurological evaluuation, complete blood count with coagulation profile, computed brain tomography, electroencephalogram, lumbar puncture with cerebrospinal fluid analysis, other relevant imaging studies), treatment details, further clarification of the event, risk factors (drugs or alcohol abuse), the evaluation did not find evidence to suggest causal relationship between the event and AZD 1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Heparin-induced thrombocytopenia test		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Gastroesophageal reflux disease	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Afebrile seizure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Thrombocytopenia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Platelet count decreased	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Immune thrombocytopenia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Intracerebral hemorrhage	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Consciousness loss	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heparin-induced thrombocytopenia test positive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

hypertension, gastroesophageal reflux disease

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

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Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

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Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210813 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021830266(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-PFIZER INC-2021830266

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021830266

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			85 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	
GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Heart attack

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	202[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
11 Days	11 Days	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Inappropriate schedule of vaccine administered	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HAD WHAT SEEMED TO BE A HEART ATTACK AND DIED.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
11 Days	11 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INAPPROPRIATE DOSING SCHEDULE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Inappropriate schedule of vaccine administered		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Inappropriate schedule of product administration		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer via COVAES. An 85-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) at the age of 85-year-old, dose 2 via an unspecified route of administration, administered in Arm Left on [redacted]021 10:00 AM (Batch/Lot Number: Unknown) as single dose for covid-19 immunisation. The patient medical history was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The COVID-19 vaccine was administered in Other (as reported). Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications (medications the patient received within 2 weeks of vaccination) included prescription anticoagulants. Historical Vaccine included bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) for covid-19 immunisation on [redacted]021 at the age of 85-years-old (DOSE 1, SINGLE, time: 08:30 AM, Anatomical Location Arm left). The patient experienced inappropriate dosing schedule on [redacted]2021 10:00, on [redacted]021 10:00 had what seemed to be a heart attack and died. Due to heart attack, treatment included CPR provided by family and by paradamics. Date of death [redacted]2021, no autopsy was done. Since the vaccination, the patient has not been tested for COVID-19.

Information about Batch/Lot number has been requested.

Follow-up (10Aug2021): This follow-up is being submitted to notify that the batch/lot number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

BNT162B2 approved under Interim Order in Canada.

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Heart attack	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

BNT162B2

Start date (B.1.8c)	End date (B.1.8e)
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	COVID-19 immunisation
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)		
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

04/26/2021 16:15

Document [redacted] Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

ATIA - 19(1)

Health Canada / Santé Canada

Canada Vigilance Adverse Reaction Reporting Form

Report of suspected adverse reactions to marketed health products in Canada

See instructions and information on adverse reaction reporting and confidentiality on Page 2.

Complete all mandatory items, marked by a *, and provide as much information as possible for the remaining items. PROTECTED WHEN COMPLETED – B**

A. Patient Information

1. Identifier [redacted]

2. Age	3. Sex*	4. Height	5. Weight
☐ Years ☐ Months	☐ Male ☑ Female	5'2" cm / feet	140 kg / lbs

B. Adverse Reaction

1. Outcome attributed to adverse reaction (Select all that apply)

- ☑ Death: 21 [redacted] (yyyy-mm-dd)
- ☐ Life-threatening
- ☐ Hospitalization
- ☐ Hospitalization – prolonged
- ☐ Disability
- ☐ Congenital malformation
- ☐ Required intervention to prevent damage/impairment
- ☐ Other:

2. Reaction date (yyyy-mm-dd): /

3. Report date (yyyy-mm-dd): 21 [redacted]

4. Describe reaction or problem*

72yr 9 hx of hypertension + fatty liver + Alcohol use. Received Covid vaccine for prophylaxis

5. Relevant tests/laboratory data (including dates (yyyy-mm-dd))

ϕ

6. Relevant history and pre-existing medical conditions (e.g. allergies, pregnancy, smoking/alcohol use, hepatic/renal dysfunction)

Alcohol Abuse
Fatty liver
hypertension

C. Suspected Health Product(s)

1. Name*, strength and manufacturer (if known)

#1 Pfizer Covid-19

#2 D was give at [redacted]

2. Dose, frequency and route used

#1	#2
IM	

3. Therapy dates (or duration)

#1 From (yyyy-mm-dd) To (yyyy-mm-dd)	#2 From (yyyy-mm-dd) - To (yyyy-mm-dd)
2021 [redacted]	

4. Indication for use

#1 Vaccine Covid-19 #2

5. Reaction abated after use stopped or dose reduced

#1 ☐ Yes ☐ No ☐ Does not apply #2 ☐ Yes ☐ No ☐ Does not apply

6. Lot #	7. Expiration
#1	#1 (yyyy-mm-dd)
#2	#2 (yyyy-mm-dd)

8. Reaction reappeared after reintroduction

#1 ☐ Yes ☒ No ☐ Does not apply #2 ☐ Yes ☐ No ☐ Does not apply

9. Concomitant health products, excluding treatment of reaction (name, dose, frequency, route used and therapy dates (yyyy-mm-dd))

Norvasc 10mg OD
Losartan 100mg OD
Had 3 glasses of wine [redacted] /21

10. Treatment of reaction, including dates (yyyy-mm-dd)

patient had no reaction. Died a natural death

D. Reporter Information

[redacted]

2. Health professional?	3. Reported to manufacturer?
☑ Yes ☐ No	☐ Yes ☑ No

** As per the Treasury Board of Canada Secretariat Government Security Policy.

A program of MedEffect™ Canada

HC Pub.: 100251 (January 2011)

Canada

Page [redacted] A2023000089

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: [redacted]
Sent: 2021-05-16 12:36 PM
To: Seguin, Michelle (HC/SC); Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: response to fax case number 000947581
Attachments: Scan 46.pdf; ATT00001.htm; Scan 47.pdf; ATT00002.htm

Hello,

Attached is the requested information. Also I sent in another one but I just faxed to the local Public Health Adverse Events at [redacted] Is this the correct fax number?

thanks
[redacted]

Page: 1,876 of/de 2,140
A2023000085

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Health Canada / Santé Canada

Tel.:
Fax:

Fax Transmission
Transmission de télécopieur

From / De: Seguin, Michelle (HC/SC)	***To / À:*** [redacted]
Date Sent: 04/28/2021 09:19:07 AM ***Pages:*** 2	***FAX Number / Numéro de télécopieur:*** [redacted]

Subject / Sujet: Health Canada Follow-Up Clarification Request (PFIZER-BIONTECH COVID-19 VACCINE)

EXTERNAL

Re: Health Canada Follow-Up Clarification Request

Good morning Dr. [redacted]

We are contacting you today to confirm receipt of the adverse event following immunization (AEFI) report submitted to the Canada Vigilance Program on April 26th, 2021.

As the result of internal Health Canada assessment process, the Canada Vigilance Assessment Team has identified the present individual case safety reports (ICSRs) where clarification is needed in order to complete the case evaluation.

Canada Vigilance Case Number	**Clarification Requested**
000947581 Suspect product: PFIZER-BIONTECH COVID-19 VACCINE Received by Health Canada on 26/04/2021	Would you kindly have any information of the following: Any information about the cause of death? Was autopsy performed? What are details of medical treatment the patient received before death? no autopsy - Cause of death NSHB Any laboratory investigation and results related to the patient's death (e.g. complete blood count with platelet count, d-dimer level, CT, MRI, Electrocardiogram etc., if available)? — NO

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- What was the patient's COVID-19 status before and at the time of her death? negative

May you please kindly respond to both myself, Michelle Séguin michelle.seguin@canada.ca in addition to the Canada Vigilance COVID-19 Vaccine generic account (hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca).

Or, if you prefer, you may fax the requested information to the **Canada Vigilance Program fax at 1-866-678-6789**; please cite **case number 00947581** if replying by this means.

If you require further information within the scope of this request, please do not hesitate to contact me.

We thank you once again for your time

Sincerely,

Michelle Séguin on behalf of,

The Canada Vigilance Program

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments
Health Canada | Santé Canada
Jeanne Mance Building | Immeuble Jeanne Mance 8th floor, Room/Pièce 808D
200 Eglantine Driveway , Pré Tunney's Pasture
Ottawa, Ontario K1A 0K9, A.L. 1908C
Telephone | Téléphone (613) 793-5750
Facsimile | Télécopieur (613) 957-0335
michelle.seguin@canada.ca

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04431362 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210716 CCYYMMDD	
	HC Initial Received Date: 20210716 CCYYMMDD	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021830493(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 202[redacted] CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	Yes
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-2021830493

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-2021830493

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Male	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 54 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04431362 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Acute respiratory distress syndrome
26.0	Overdose

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
1545 Hours	1545 Hours	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Acute respiratory distress syndrome	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Acute respiratory distress syndrome	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Neck pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Neck pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Oxygen saturation low	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulmonary edema	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulmonary edema	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Spinal cord infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Spinal cord infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Swelling	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RISPERIDONE	
Active Substance names (B.4.k.2.2)		
risperidone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

OXYGEN DISTRESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Acute respiratory distress syndrome		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Acute respiratory distress syndrome		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
1545 Hours	1545 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE HEADACHES

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Headache
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Headache

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE NECK PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Neck pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Neck pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SWOLLEN SPINE BEHIND THE ESOPHAGAS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Swelling
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Swelling

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INFECTION IN SPINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Spinal cord infection
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Spinal cord infection

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FLUID IN LUNGS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pulmonary edema
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pulmonary oedema

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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		Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOW OXYGEN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Oxygen saturation low		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Oxygen saturation decreased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Summary (B.5)

Case narrative (B.5.1)

This is spontaneous report received via COVAES from a contactable consumer.
A 54-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number was not reported), in arm right on [redacted]2021 at 15:00 (at 54 years) as single dose for covid-19 immunisation . Medical history included Downe Syndrome (as reported). Concomitant medication included risperidone taken for an unspecified indication, start and stop date were not reported. On [redacted]2021 at 15:00 patient experienced severe headaches, severe neck pain, swollen spine behind the esophagas, infection in spine, all this causing to be bedridden and then (date unspecified in 2021)fluid in lungs, causing pneumonia, then causing low oxygen and needing to be on oxygen 24/7 (as reported). Events required emergency room/department or urgent care. Patient was hospitalized for 36 days in 2021 due to the events, that are also serious as life threatening. On [redacted]2021 patient had oxygen distress serious per hospitalized and life threatening. Patient was treated with IV antibiotics, oxygen,steroid and puffers.Patient died on [redacted]2021 due to overloaded by medication and oxygen distress. Outcome of oxygen distress was fatal; outcome of the other events was not recovered. It was unknown if an autopsy was done. No follow-up attempts are possible, information about batch number cannot be obtained.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021 CCYY	Oxygen saturation	low	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Down's syndrome	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1): 26.0
Episode name (B.1.7.1a.2): Acute respiratory distress syndrome
Start date (B.1.7.1c)
Continuing (B.1.7.1d)
End date (B.1.7.1f)
Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1): 26.0
Episode name (B.1.7.1a.2): Overdose
Start date (B.1.7.1c)
Continuing (B.1.7.1d)
End date (B.1.7.1f)
Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)
Start date (B.1.8c)
End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)
Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)
Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)
DOB of Parent (B.1.10.2.1)
Age (B.1.10.2.2)
LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)
Height (cm) (B.1.10.5)
Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)
Medical history (B.1.10.7.1a.2)
Start date (B.1.10.7.1c)
Continuing (B.1.10.7.1d)
End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)
Drug start date (B.1.10.8c)
Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)
Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)
Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210915 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021846052(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210705 CCYYMMDD	20210910 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021846052

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021846052

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	COVID-19
26.0	Drug ineffective

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	COVID-19	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Drug ineffective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19/DELTA VARIANT/POSITIVE HAVE VERY MILD SYMPTOMS/ONE DEATH HAS BEEN REPORTED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug ineffective		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug ineffective		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COVID-19/DELTA VARIANT/POSITIVE HAVE VERY MILD SYMPTOMS/ONE DEATH HAS BEEN REPORTED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	COVID-19		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	COVID-19		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from two contactable healthcare professionals. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number and expiration date unknown), dose 1, single and dose 2, single, both received via an unspecified route of administration on unspecified dates for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced COVID-19 on an unspecified date. The reporter stated that there was an outbreak of the delta variant after 2 doses of BNT162B2 was received. All residents were positive and have very mild symptoms although one death has been reported. The patient underwent a COVID-19 virus test on an unspecified date with the following result: positive (Delta variant). The patient died on an unspecified date. It was not reported if an autopsy was performed.

Follow-up (10Sep2021): This follow-up is being submitted to notify that the batch/lot number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the information available and close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events . The case will be reassessed once new information is available

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
	COVID-19 virus test	positive

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes

Results of tests and procedures (B.3.2)

SARS-CoV-2 test():Delta variant

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	COVID-19	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Drug ineffective	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Other health professional
Literature reference(s) (A.2.2)		
Study name (A.2.3.1)	Project No	
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20220819 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GLAXOSMITHKLINE-CA2021AMR157705(3)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220816 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-GSKCCFAMERS-Case-01115696_AE-65718

Other case identifiers in previous transmission? (A.1.11) Yes

Duplicate Source(s) (A.1.11.1) 01052547635	**Duplicate Case identifiers (A.1.11.2)** CA-GLAXOSMITHKLINE-CA2021AMR157705

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) E2B_03809929, (2) , (2) E2B_03809929, (2) , (2) E2B_03809929

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14) Yes

Source (A.1.4) MAH - GLAXOSMITHKLINE

Patient (B.1)

Patient Initial (B.1.1) PRIVACY	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)** 56 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Asthmatic attack
26.0	Missed dose

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** MEPOLIZUMAB	
Active Substance names (B.4.k.2.2) mepolizumab		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 100 Milligram		
Dosage text (B.4.k.6) 100 mg, Z every 4 weeks		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Subcutaneous	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Eosinophilic asthma
Start date of drug (B.4.k.12) 20210427 CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)

MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Asthmatic attack	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** No
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Asthmatic attack	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Missed dose	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** No
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Missed dose	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Unknown

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 prophylaxis
Start date of drug (B.4.k.12) 20210412 CCYYMMDD	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) TOZINAMERAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Suspension Intramuscular (Vial contains 6 doses of 0.3 ml after dilution)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK (Vial contains 10 doses of 0.5 ml)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ASTHMA ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Asthmatic attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Asthma		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
		2021[redacted] CCYYMMDD	
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DID NOT RECEIVE THE DOSE ON THIS DATE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Missed dose		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Product dose omission issue		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
56 Days		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This case was reported by a physician via regulatory authority and described the occurrence of asthmatic attack in a 56-year-old female patient who received mepolizumab solution for injection in pre-filled pen for eosinophilic asthma.

Co-suspect products included mepolizumab autoinjector device administration system (batch number Unk, expiry date unknown) for eosinophilic asthma, tozinameran (Pfizer-Biontech Covid-19 Vaccine) for covid-19 prophylaxis, covid-19 vaccine for covid-19 prophylaxis, tozinameran (Comirnaty) for covid-19 immunization and covid-19 vaccine nrvv ad (chadox1 ncov-19) (Vaxzevria) unknown for covid-19 immunization.

On 27th April 2021, the patient started mepolizumab (subcutaneous) 100 mg (see dose text) and mepolizumab autoinjector device. On 12th April 2021, the patient started Pfizer-Biontech Covid-19 Vaccine at an unknown dose and frequency. On [redacted] 2021, the patient started covid-19 vaccine at an unknown dose and frequency. On an unknown date, the patient started Comirnaty (unknown) at an unknown dose and frequency and Vaxzevria (intramuscular) at an unknown dose and frequency. On [redacted] 2021, 56 days after starting mepolizumab and mepolizumab autoinjector device, the patient experienced missed dose (serious criteria death). On an unknown date, the patient experienced asthmatic attack (serious criteria death). On [redacted] 2021, the outcome of the asthmatic attack was fatal. On an unknown date, the outcome of the missed dose was fatal. The subject died on [redacted] 2021. The reported cause of death was asthmatic attack and missed dose.

It was unknown if the reporter considered the asthmatic attack and missed dose to be related to mepolizumab and mepolizumab autoinjector device. This report is made by GSK without prejudice and does not imply any admission or liability for the incident or its consequences.

Linked case(s) involving the same patient: CA2020AMR168025, CA2021AMR113784

GSK Receipt Date: [redacted] 2021
Reporter's Comments: Initial with date [redacted] 2021 and follow up with date [redacted] 2021 processed together. This case was received from physician via Vista Patient Support Program (Nucala) patient support programs on [redacted] 2021. Patient had her first COVID vaccine on 15 April 2021. Patient started her first Nucala injection on 27 April 2021. Patient was due for next COVID injection on [redacted] 2021 however this was pushed up to [redacted] 2021. MD (Doctor of medicine) informed that the patient passed away from a respiratory illness on [redacted] 2021. Last Nucala injection was given on [redacted] 2021. It was reported as: Patient was initially booked for next COVID injection on [redacted] 2021, but could obtain an earlier appointment and received COVID vaccine on [redacted] 2021. It was unknown if the reporter considered the asthmatic attack to be related to covid-19 vaccine. The patient was taking mepolizumab as Nucala (auto-injector). This case was linked to cases CA2021AMR113784 and CA2020AMR168025 as same patient.

Follow up information was received from Physician via sale rep on [redacted] 2021. Physician reported that a patient died following asthma attack. Patient took Nucala from 4 months and had second dose of Covid-19 vaccine the same day as the last Nucala injection. Patient died about a month later, on [redacted] 2021. The Physician was now concerned by the safety of Nucala. Lot number was not available. Format of Nucala was not available. Suspect product was started 4 months ago, patient was also with Nucala PSP (patient support program). Sales rep tried to submit the AE (adverse event) through the system directly to PV (pharmacovigilance) but she was not sure it went through (no ref number was received) so she called Medical Information. Consent to follow-up granted. No other information provided.

Follow up information was received from patient support program on 23 July 2021:
The nurse reported that the patient received the first dose of Pfizer COVID-19 vaccine on 12 April 2021. The patient received the first dose of Nucala on 27 April 2021 and the second dose of Nucala on 25 May 2021. The patient received the second dose of COVID- 19 vaccine (brand unknown) on [redacted] 2021. The patient was planned to receive the third dose of Nucala on [redacted] 2021 however did not receive the dose on this date as physician authorization due to proximity to the COVID-19 vacccine was pending. The physician has recommended an autopsy be performed. . It was unknown if the reporter considered the asthmatic attack to be related to Covid-19 vaccine and Pfizer COVID-19 vaccine. It was unknown if the reporter considered the asthmatic attack to be related to Covid-19 vaccine and Pfizer COVID-19 vaccine.

Follow-up information received on 16-Aug-2022. This follow-up was considered significant.
Reporter's Comments: It was unknown if the reporter considered the asthmatic attack to be related to Comirnaty and Vaxzevria.
Summary of Changes: Added suspect product details. Updated causality for missed dose and cause of death.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Asthma and Product dose omission issue are unlisted events which are considered unrelated to GSK drug Mepolizumab and mepolizumab autoinjector device.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)		Test result (B.3.1d)
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

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Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Asthmatic attack	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Missed dose	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**

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Canada Vigilance AER#:	E2B_04459575 (2)	Page#11

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Mepolizumab Patient Support Program	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
Mepolizumab PSP	Other studies

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04466849 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210726 CCYYMMDD
	HC Initial Received Date:	20210726 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021887750(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210712 CCYYMMDD	20210712 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021887750

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021887750

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			24 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04466849 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Died in sleep

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Died in sleep	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Died in sleep	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Canada Vigilance AER#:	E2B_04466849 (0)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PASSED AWAY IN HIS SLEEP AND DIDN'T WAKE UP MONDAY MORNING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Died in sleep
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable physician for a 24-year old-male consumer (patient), communicated to a sales representative regarding product BNT162B2.

A 24-year-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 Vaccine, Formulation: solution for injection, Lot number and expiration date was not reported), via unspecified route of administration on unknown date as dose number unknown, single for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter stated that a healthy and active 24 year old patient who received the Pfizer vaccine on a Sunday passed away in his sleep and didn't wake up Monday morning. Event took place after use of product. It was unknown if autopsy was performed.

No follow-up attempts are not possible. No further information expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The information on the circumstances of the patient's death is too limited to perform a meaningful company causality assessment: this event is handled as related to the suspect product BNT162B2 as a cautionary measure and for reporting purposes.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Died in sleep

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Physician
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04471840 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210914 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021901560(3)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210713 CCYYMMDD	20210831 CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-2021901560

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-2021901560

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			69 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04471840 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Multi organ failure

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EX0904	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
24 Days	24 Days	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
ExpDT=31-JUL-2021		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	CVA	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	CVA	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	DVT	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	DVT	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Immune-mediated thrombocytopenia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Immune-mediated thrombocytopenia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Multi organ failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Multi organ failure	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MULTI SYSTEM ORGAN FAILURE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Multi organ failure		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Multiple organ dysfunction syndrome		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
24 Days	24 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUSPECTED VITT THROMBOCYTOPENIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Immune-mediated thrombocytopenia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Immune thrombocytopenia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
11 Days	11 Days	Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DVT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	DVT		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Deep vein thrombosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
11 Days	11 Days	Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CVA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	CVA		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebrovascular accident		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
11 Days	11 Days	Unknown	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable pharmacist. A 69-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly at age of 69-years-old on [redacted]2021 (Lot Number: EX0904 and Expiration Date: 31Jul2021) as single dose for covid-19 immunisation. The patient medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient experienced multi system organ failure on [redacted]2021, Suspected (VITT) Vaccine-induced Immune Thrombotic Thrombocytopenia, Deep vein thrombosis (DVT), Cerebrovascular accident (CVA), all on [redacted]2021. The patient was hospitalized for Suspected Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT), Deep vein thrombosis (DVT), Cerebrovascular accident (CVA) for 13 days. Since the vaccination, the patient had been tested for COVID-19. The patient underwent lab tests and procedures which included Nasal Swab: negative. Treatment received for the events included anticoagulation initially. Events resulted in Emergency room/department or urgent care. The patient died on [redacted]2021 due to multi system organ failure. An autopsy was not performed. Outcome of other events was unknown.
On 31Aug2021, investigation result was received regarding consumers complaint about (PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE) Lot: EX0904, Expiration Date: 31Jul2021.Brief complaint description: Product quality investigation request. Lot Number: EX0904. Since the vaccination, has the patient been tested for COVID-19?:Yes,Reasonably Suggest Device Malfunction: No, Severity of Harm: N/A, Complaint Class:External Cause Investigation,Complaint Sub Class:Adverse Event Safety. Request For Investigation, Root Cause: Non-assignable, Process related: No, Final Confirmation Status: Not confirmed, Vendor Related: No ,Lot-Specific Trend Identified: No, Lot Trend Assmt & Rationale: Lot history period: as COVID was only introduced on the market as of DEC 2020, all available complaint data was reviewed until 31Aug2021. Lot history parameters: FP-batch: EX0904. The complaint history has been reviewed for the reported batch. Based on the complaint subclass of the received complaint, complaints with subclasses Adverse Event Safety Request For Investigation and Lack Of Effect were included. 1 complaint has been received since the introduction on the market. Trending regarding adverse event/LOE investigations is performed by Global Safety.,Lot Trend Actions taken: No actions are required.;Other trend Identified?:No ; Other Trend Assmt. & Rationale?: The complaint history has been reviewed for the reported product and subclass Adverse Event Safety Request For Investigation and Lack Of Effect . 13370 similar complaints have been received since the introduction on the market, resulting in a cpm of
88,45. Trending regarding adverse event/LOE investigations is performed by Global Safety. No actions are required. Site Sample Status:Not received ;Summary of Investigation from Pluurs division was The PGS Puurs investigation could not indicate a probable root cause for the complaint to be related to the production process of the involved batch. All reviewed records for the involved batch indicated that the batch met the established requirements at time of release. No impact assessment is required according to SOP-67372 v9.0. No corrective or preventive actions were identified as all reviewed records for the involved batch indicated that the batch met the established requirements at time of release.; Investigational report conclusion from Puurs division was The complaint for PFIZER-BIONTECH COVID-19 VACCINE was investigated. The investigation included reviewing the involved batch records, deviation investigation, an analysis of the complaint history for the reported lot and product type. The final scope was determined to be the associated lot(s) of the reported lot EX0904. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation and stability. PGS Puurs concludes that the reported defect is not representative of the quality of the batch and the batch remains acceptable. The NTM process determined that no regulatory notification was required. The reported defect could not be confirmed. No root cause or CAPA were identified as the complaint was not confirmed.

Follow-up (11Aug2021): New information was received via fax from a contactable Health Care professional (Pharmacist) includes: autopsy information (An autopsy was not performed).

Follow-up (31Aug2021): New information received from product quality complaint team includes: suspect drug details (expiration date) and investigation result.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the plausible temporal relation, the association between the events of Multi-organ failure, Immune-mediated thrombocytopenia, Deep Vein thrombosis and Cerebrovascular Accident and the suspect product of BNT162B2 cannot be completely ruled out.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	COVID-19 virus test	Negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)

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26.0	Multi organ failure

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210831 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202100923666(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210718 CCYYMMDD	20210827 CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202100923666

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202100923666

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			65 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Acute leukemia NOS

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
76125 Minutes	76125 Minutes	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Acute leukemia NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Acute leukemia NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhage intracerebral	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhage intracerebral	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT DEVELOPED ACUTE LEUKEMIA WHICH WAS ONLY DIAGNOSED [redacted] AFTER A BRAIN HEMMORHAGE.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hemorrhage intracerebral		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cerebral haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
76125 Minutes	76125 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT DEVELOPED ACUTE LEUKEMIA WHICH WAS ONLY DIAGNOSED [redacted] AFTER A BRAIN HEMMORHAGE.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Acute leukemia NOS		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Acute leukaemia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
90165 Minutes	90165 Minutes	Fatal	

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable consumer via COVAES. A 65-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: solution for injection, Lot number: Unknown) via an unspecified route of administration on [redacted]2021 at 09:15 (at the age of 65-year-old) as dose number unknown, single for COVID-19 immunization. The patient's medical history was not reported. The patient did not receive any other medications within 2 weeks of vaccination. Patient did not receive any other vaccines within 4 weeks prior to covid vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. On [redacted]2021 at 06:00, the patient developed brain haemorrhage and on [redacted]2021, the patient diagnosed with acute leukaemia. The adverse events resulted into emergency room/department or urgent care. The patient was hospitalized for 2 days. Treatment included for adverse event was blood cleaning machine. The patient underwent lab tests and procedures which included nasal swab: negative on 27May2020. The patient died on [redacted]2021. The cause of death was brain haemorrhage resulting from acute leukaemia. It was not reported if an autopsy was performed.

The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.

Follow-up (27Aug2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)
20200527 CCYYMMDD	Investigation	Negative

Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Acute leukemia NOS

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04507910 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211027 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202100929854(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210720 CCYYMMDD	20211021 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202100929854

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202100929854

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04507927, (2) E2B_04507927, (2) E2B_04507927, (2) E2B_04507927

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04507910 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Anaphylactic reaction

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2) tozinameran		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Anaphylactic reaction	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Anaphylactic reaction	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Canada Vigilance AER#:	E2B_04507910 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ANAPHYLACTIC REACTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Anaphylactic reaction
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Anaphylactic reaction

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the second of two reports.

A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter stated she has a relative and she had an anaphylactic reaction to the vaccine, and she died on an unspecified date. The outcome of the event was fatal. It was unknown if an autopsy was performed.

The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

Follow-up (21Oct2021): This follow-up is being submitted to notify that the lot/batch number for all doses is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Anaphylactic reaction	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Canada Vigilance AER#:	E2B_04507910 (1)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_04507910 (1)	Page#6

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04509824 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210916 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202100991812(2)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 2021[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20210908 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	Yes
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-PFIZER INC-202100991812

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) PFIZERINC	**Duplicate Case identifiers (A.1.11.2)** CA-PFIZER INC-202100991812

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04629806, (2) E2B_04508307, (2) E2B_04508307, (2) E2B_04629806

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)**	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1) 2 Weeks		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04509824 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Fetal growth abnormality
26.0	Maternal exposure during pregnancy, first trimester

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	FA9093	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Transplacental	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
577 Hours		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
ExpDT=31-OCT-2021		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fetal growth abnormality	

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Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fetal growth abnormality	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MISSED MISCARRIAGE - FETAL GROWTH STOPPED AT 7 WEEKS AND WAS DIAGNOSED AT 11 WEEKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Maternal exposure during pregnancy, first trimester		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Maternal exposure during pregnancy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
577 Hours		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MISSED MISCARRIAGE - FETAL GROWTH STOPPED AT 7 WEEKS AND WAS DIAGNOSED AT 11 WEEKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fetal growth abnormality		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Foetal growth abnormality		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

ATIA - 19(1)

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Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from a contactable consumer (patient's mother). This consumer reported information for both mother and fetus. This is a fetus report.

A fetus patient of an unspecified gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), transplacental, administered in Arm Left on [redacted]021 17:15 (Lot Number: FA9093, Expiration date: 31Oct2021) as dose 2, single, transplacental, administered in Arm Right on [redacted]2021 17:30 (Lot Number: EW0193, Expiration Date: 30Sep2021) as dose 1, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The mother is a 37-year-old female, last menstrual period date [redacted]021), Pregnancy Due Date [redacted]022). Facility where the most recent COVID-19 vaccine was administered: Public Health Clinic/Veterans Administration facility. Mother had missed miscarriage - fetal growth stopped at 7 weeks and was diagnosed at 11 weeks. Adverse event resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/ department or urgent care. Treatment was given. The patient died on [redacted]2021. It was not reported if an autopsy was performed.

Investigational report conclusion from Kalamazoo division was The complaint for an adverse event requested by safety with the use of the PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE lot EW0193 was investigated. The investigation included reviewing the manufacturing and packaging batch records, retained reference samples, deviation investigations and an analysis of the complaint history for the reported lot. The final scope was determined to be the reported finished goods lot EW0193, fill lot EP8739, and the bulk formulated drug product lot EP8620. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality. No root cause or CAPA were identified as the complaint was not confirmed.

Conclusion: The complaint for an adverse event requested by safety with the use of the PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE lot EW0193 was investigated. The investigation included reviewing the manufacturing and packaging batch records, retained reference samples, deviation investigations and an analysis of the complaint history for the reported lot. The final scope was determined to be the reported finished goods lot EW0193, fill lot EP8739, and the bulk formulated drug product lot EP8620. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality. No root cause or CAPA were identified as the complaint was not confirmed.

Summary of Investigation: The initial scope of the investigation was limited to the reported finished goods lot FA9093, fill lot EY0549, and the bulk formulated drug product lot EP8653. Based on the results of this investigation, the scope was not expanded. Manufacturing and packaging batch records were examined. There were no planned or unplanned deviations recorded during the manufacture of the lot that may have impacted product quality. Pfizer Kalamazoo QO did not receive a complaint sample or photographs for examination. The complaint was not confirmed. No related quality issues were identified during the investigation. There were no planned or unplanned deviations recorded during the manufacture of the lot that were determined to have an impact on product quality. A review of the manufacturing and packaging records confirmed all processing steps met established requirements, all noted defects were within limits and discarded, elapsed time tracking was within limits, and the freezer storage was acceptable. There were no product quality defects observed during the examination of retained reference samples. There is no impact to the quality of the lot. It is unknown how the product was handled, stored, or administered after it left the Kalamazoo site.

Conclusion: The complaint for an adverse event requested by safety with the use of the PFIZER-BIONTECH COVID-19 VACCINE lot FA9093 was investigated. The investigation included reviewing the manufacturing and packaging batch records, retained reference samples, deviation investigations and an analysis of the complaint history for the reported lot and product type. The final scope was determined to be the reported finished goods lot FA9093, fill lot EY0549, and the bulk formulated drug product lot EP8653. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality. No root cause or CAPA were identified as the complaint was not confirmed.

Follow-up (06Sep2021): Follow-up attempts completed. No further information expected.

Follow up (08Sep2021, 08Sep2021): New information received from product quality complaint team includes: suspect drug information, investigation result.

No follow-up attempts are needed. No further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fetal growth abnormality	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Maternal exposure during pregnancy, first trimester	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04509824 (1)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
Reporter street (A.2.1.2c)	
Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04534786 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210907 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A674645()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210809 CCYYMMDD	20210906 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A674645

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	000947601 [redacted] CA-AstraZeneca-2021A674645

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female	170 Centimeter	80 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			48 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Canada Vigilance AER#:	E2B_04534786 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Headache
26.0	Nausea
26.0	Somnolence

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VAXZEVRIA VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510847 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	FLOVENT HFA	
Active Substance names (B.4.k.2.2)		
fluticasone propionate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
metered dose		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	FLURAZEPAM HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
flurazepam hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) SALBUTAMOL	
Active Substance names (B.4.k.2.2) salbutamol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TEVA FENTANYL	
Active Substance names (B.4.k.2.2) FENTANYL		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) NABILONE	
Active Substance names (B.4.k.2.2) nabilone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) DULOXETINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2) duloxetine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Delayed release		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	LEVOTHYROXINE SODIUM	
Active Substance names (B.4.k.2.2)		
levothyroxine sodium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) MELATONIN	
Active Substance names (B.4.k.2.2) melatonin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	LEVOMEPROMAZINE MALEATE	
Active Substance names (B.4.k.2.2)		
levomepromazine maleate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ONDANSETRON HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
ondansetron hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Tablet	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PMS RABEPRAZOLE EC	
Active Substance names (B.4.k.2.2)		
RABEPRAZOLE SODIUM		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Enteric coated		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Tablet	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) PREGABALIN	
Active Substance names (B.4.k.2.2) pregabalin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RANITIDINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
ranitidine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Tablet	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	TRAZODONE	
Active Substance names (B.4.k.2.2) trazodone hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7) Tablet	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) SANDOZ DICLOFENAC	
Active Substance names (B.4.k.2.2) diclofenac sodium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Headache		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Headache		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Nausea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Nausea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SOMNOLENCE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Somnolence		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Somnolence		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via physician concerning a 48-year-old female patient of Unknown ethnic origin (height 67 in, weight 80 kg).

No medical history was reported. Concomitant medication included fluticasone propionate, flurazepam hydrochloride, salbutamol sulfate, fentanyl, nabilone, duloxetine hydrochloride, levothyroxine sodium, melatonin, levomepromazine maleate, ondansetron hydrochloride, rabeprazole sodium, pregabalin, ranitidine hydrochloride, trazodone hydrochloride and diclofenac sodium.

The patient received Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN) once/single administration, via intramuscular route, for immunisation on an unknown date.

On an unknown date, the patient experienced headache (preferred term: Headache), nausea (preferred term: Nausea) and somnolence (preferred term: Somnolence).

Action taken with Astrazeneca Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml was not applicable

On an unspecified date the patient died and the cause of death was headache, nausea and somnolence. It was not known whether an autopsy was performed.

The events were considered serious (death).

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The Astra-Zeneca COVID-19 vaccine is an AstraZeneca Canada inc product authorized under the interim order.

Summary of follow-up information received by AstraZeneca/MedImmune 06-SEP-2021 A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via physician: Health Authority Reference number was captured in the Reporter Case ID field and narrative updated.
CAUSE OF DEATH: HEADACHE CAUSE OF DEATH: NAUSEA CAUSE OF DEATH: SOMNOLENCE HEADACHE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes NAUSEA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes SOMNOLENCE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes
The Astra-Zeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Headache, nausea and somnolence are listed adverse event for AZD1222. However, as the SAE is reported with the seriousness criteria of Death the event is considered unexpected. Cause of death was reported as headache, nausea, and somnolence. Case is confounded by polypharmacy. Due to limited information on circumstances leading to death, clinical course, concurrent diseases, relevant medical and family history, vaccine AZD122 administration date, events date, etiologic and diagnostic workup, the evaluation did not find evidence to suggest a causal relationship between the events and vaccine AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Headache	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Nausea	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Somnolence	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	PRIVACY	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04551664 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210813 CCYYMMDD
	HC Initial Received Date:	20210813 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101022711(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Study		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210809 CCYYMMDD	20210809 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101022711

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Health Canada PFIZERINC	000940311 CA-PFIZER INC-202101022711

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) 000940311

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			95 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cardiac failure congestive
26.0	Dyspnoea

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE NUMBER UNKNOWN, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cardiac failure congestive	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyspnoea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** ELIGARD	
Active Substance names (B.4.k.2.2) leuprolide acetate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 22.5 Milligram,1 every 3 (Months)		
Dosage text (B.4.k.6) 22.5 mg, every 3 months		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Subcutaneous	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Prostate cancer
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CARDIAC FAILURE CONGESTIVE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cardiac failure congestive		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cardiac failure congestive		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSPNOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dyspnoea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

This is a Non-Interventional Study report from a contactable Consumer. This is a report received from the Health Canada Regulatory Authority via an on-line database search. Regulatory authority report No 000940311. This information was initially reported to Health Canada between 24Feb2021 and 06Apr2021 from an unknown Market Authorization Holder AER# unspecified

A 95-year-old male subject received bnt162b2 (COVID-19 VACCINE - MANUFACTURER UNKNOWN), intramuscular on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation; leuprorelin acetate (ELIGARD), subcutaneous from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 22.5 mg, every 3 months; subcutaneous from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 22.5 mg, every 3 months for prostate cancer. Medical history included prostate cancer from an unknown date. The subject's concomitant medications were not reported. The subject experienced cardiac failure congestive, dyspnoea on an unspecified date. The action taken in response to the event (s) for leuprorelin acetate was unknown. The outcome of the event was fatal. The subject died on an unspecified date. It was not reported if an autopsy was performed

The reporter's assessment of the causal relationship of the events with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment

Pfizer is the Marketing authorization holder of COVID-19 VACCINE in the country of incidence .This may be a duplicate report if another marketing authorization holder of COVID-19 VACCINE has submitted the same report to regulatory authorities.

No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.
COVID-19 Vaccine - Manufacturer Unknown approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the available information and the strong drug event temporal association, a possible contributory role of suspect product BNT162B2 to development of events Cardiac failure congestive and Dyspnoea cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Prostate cancer	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac failure congestive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Consumer/other non health professional
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3) Other studies	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)	
Department (A.3.1.3a)		Title (A.3.1.3b)	
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)	
Street (A.3.1.4a)			
City (A.3.1.4b)		State (A.3.1.4c)	
Postcode (A.3.1.4d)		Country code (A.3.1.4e)	
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)	
Email Address (A.3.1.4l)			

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI*

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
48 ans _____ mois	☐ Homme ■ Femme	_____ cm 5 pi 7 po	80 kg _____ lbs _____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

ATCD Fibromyalgie, dépression, Hypothyroïdie

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]		

4. Adresse	5. Courriel
[redacted]	

6. Langue préférée	7. Organisation (le cas échéant)
■ français ☐ anglais	[redacted]

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ■ Médecin ☐ Pharmacien

☐ Autre professionnel de la santé (spécifier) : _____

9. Cela a-t-il été déclaré au fabricant?

☐ Oui ■ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

- ■ Décès (fournir la date) 2021 [redacted]
- ☐ Met la vie en danger
- ☐ Hospitalisation
- ☐ Prolongation d'une hospitalisation
- ☐ Incapacité
- ☐ Malformation congénitale
- ☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire

☐ Oui ■ Non ☐ Inconnu

☐ En cours de rétablissement (expliquer) : _____

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)
2021 [redacted]	

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

Céphalée, nausées et somnolence post-vaccination. Patiente décède le [redacted] 2021. Arrivée décédée à l'hôpital. Pas de cause de décès évident. Cas soumis au coroner # cas : [redacted]

D) Produit de santé soupçonné

1. Nom du produit	2. Concentration	3. Fabricant
Vaccin Covid		Astra Zeneca

4. N° du lot	5. N° du DIN / N° du NPN
?	?

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
■ Canada ☐ États-Unis ☐ Autre (spécifier) : _____	☐ Pharmacie ☐ Épicerie ☐ Internet ■ Autre (spécifier) : Vaccination

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2021 [redacted]	N/A

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
Injection intra-muaculaire	1x	IM

13. Pourquoi le produit a-t-il été pris/prescrit?

Prévention COVID-19

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☐ Oui ☐ Non	☐ Oui ☐ Non ■ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ☐ Non ■ Ne s'applique pas	☐ Oui ☐ Non ■ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

- ☐ Certain
- ☐ Probablement/vraisemblablement
- ■ Possiblement
- ☐ Pas disponible / incapable de vérifier
- ☐ Improbable
- ☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

Inconnu. C.f. liste de médication ci-jointe.

20. Tests/données de laboratoire pertinents

* Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

Pub. : 150143 | Date : avril 2020

Santé Canada Health Canada

A2023000085

Canada

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ATIA - 19(1)

[redacted]

No de dossier local:

1972 [redacted]

Imprimé par : [redacted]
Date d'Impression : **2021** [redacted] **21:18**

Médicaments actifs ou complétés derniers 30 jours [redacted]

Statut	Type	Ind.	Médicament (Nom commercial)	Posologie	Ord.	DR	Dernière délivrance	Délai* (jrs)	Qté dél.	Commentaire
			DULOXETINE 60MG CAPSULE ENT. (JAMP DULOXETINE 60MG CAPSULE ENT.)	PRENDRE 2 CAPSULE UNE FOIS PAR JOUR, AU SOUPER	2021[redacted]	53	202[redacted]	2	14	
			TRAZODONE 100MG COMPRIME (TRAZODONE 100MG COMPRIME)	1 COMPRIME 1 FOIS PAR JOUR 1/2 HEURE AVANT COUCHER	202[redacted]	53	2021[redacted]	2	7	
			LEVOTHYROXINE 88MCG COMPRIME (SYNTHROID 88MCG COMPRIME)	1 COMPRIME 1 FOIS PAR JOUR LE MATIN	2020/12/10	36	2021[redacted]	2	7	
			PREGABALINE 50MG CAPSULE (PREGABALIN 50MG CAPSULE)	1 CAPSULE 2 FOIS PAR JOUR MATIN ET COUCHER	2020/10/06	27	2021[redacted]	2	14	
			PREGABALINE 150MG CAPSULE (PREGABALIN 150MG CAPSULE)	1 CAPSULE PAR LA BOUCHE 1 FOIS PAR JOUR AVANT LE COUCHER AVEC 1 CAPSULE DE 50MG DOSE TOTALE 200MG	2020/10/06	27	202[redacted]	2	7	
			PREGABALINE 75MG CAPSULE (PREGABALIN 75MG CAPSULE)	1 CAPSULE PAR LA BOUCHE 1 FOIS PAR JOUR LE MATIN AVEC 1 CAPSULE DE 50MG DOSE TOTALE 125MG	2020/10/06	27	2021[redacted]	2	7	
			RABEPRAZOLE 20MG COMP. ENT. (PMS RABEPRAZOLE EC 20MG COMP. ENT.)	1 COMPRIME 1 FOIS PAR JOUR 30 MINUTES AVANT LE DEJEUNER **PP206**	2020/09/28	28	2021[redacted]	2	7	

* L'information sur le délai permet d'identifier le laps de temps écoulé depuis la dernière délivrance. Cette information peut notamment permettre de repérer des médicaments qui sont actifs [redacted]mais qui pourraient ne plus être pris par l'usager.

Ce document fait partie intégrante du dossier local de l'usager lorsqu'il y est consigné.
Dès lors, les règles de confidentialité et de conservation applicables à ce document sont celles prévues pour ce dossier local.

ATIA - 19(1)

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[redacted]

No de dossier local:

1972 [redacted]

Imprimé par : [redacted]

Date d'Impression : **2021** [redacted] **21:18**

Médicaments actifs ou complétés derniers 30 jours [redacted]

Statut	Type	Ind.	Médicament (Nom commercial)	Posologie	Ord.	DR	Dernière délivrance	Délai* (jrs)	Qté dél.	Commentaire
			MELATONINE 10MG COMPRIME S/L (MELATONINE 10MG COMPRIME S/L)	1 COMPRIME PAR LA BOUCHE AU COUCHER SI BESOIN (DS DISPILL)	2020/09/28	28	2021/[redacted]	2	7	
			RANITIDINE 150MG COMPRIME (MAR RANITIDINE 150MG COMPRIME)	PRENDRE 1 COMPRIME 2 FOIS PAR JOUR AU DINER ET AU COUCHER	2020/09/28	28	2021[redacted]	2	14	
			METHOTRIMEPRAZINE 5MG COMPRIME (METHOPRAZINE 5MG COMPRIME)	1 COMPRIME 1 FOIS PAR JOUR 1/2 HEURE AVANT COUCHER	2020/09/28	27	2021/[redacted]	2	7	
			SALBUTAMOL-INH 100MCG INHALATEUR (TEVA SALBUTAMOL HFA 100MCG INHALATEUR)	PRENDRE 2 INHALATIONS 4 FOIS PAR JOUR SI BESOIN	2020/09/28	6	2021/[redacted]	10	200	
			DICLOFENAC 50MG SUPPOSITOIRE (SANDOZ DICLOFENAC 50MG SUPPOSITOIRE)	1 SUPPOSITOIRE 2 FOIS PAR JOUR SI BESOIN	2020/09/28	2	2021/[redacted]	10	30 U	
			NABILONE 1MG CAPSULE (TEVA NABILONE 1MG CAPSULE)	1 CAO PAR LA BOUCHE 2 FOIS PAR JOUR SI BESOIN **SERVIR 60 A LA FOIS**	2020/09/28	5	2021[redacted]	10	60	
			FENTANYL-TRANSDERMIQUE 100MCG/HR TIMBRE-72H (TEVA FENTANYL 100MCG/HR TIMBRE-72H)	1 TIMBRE AUX 3 JOURS (SERVIR 10 PAR MOIS) *PREPARER/ APPELER/ LIVRER*	2020/09/28	5	2021/[redacted]	10	10 U	

* L'information sur le délai permet d'identifier le laps de temps écoulé depuis la dernière délivrance. Cette information peut notamment permettre de repérer des médicaments qui sont actifs a[redacted] mais qui pourraient ne plus être pris par l'usager.

Ce document fait partie intégrante du dossier local de l'usager lorsqu'il y est consigné.
Dès lors, les règles de confidentialité et de conservation applicables à ce document sont celles prévues pour ce dossier local.

ATIA - 19(1)

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[redacted]

No de dossier local:

1972 [redacted]

Imprimé par : [redacted]

Date d'impression : **2021/** [redacted] **21:16**

Médicaments actifs ou complétés derniers 30 jours [redacted]

Statut	Type	Ind.	Médicament (Nom commercial)	Posologie	Ord.	DR	Dernière délivrance	Délai* (jrs)	Qté dél.	Commentaire
			FLUTICASONE-PROPIONATE-INH 125MCG INHALATEUR (FLOVENT HFA 125MCG INHALATEUR)	2 INHALATIONS 2 FOIS PAR JOUR MATIN ET SOIR (BIEN RINCER LA BOUCHE APRES UTILISATION)	2020/09/28	6	2021[redacted]	10	120	
			ONDANSETRON 8MG COMPRIME (ONDANSETRON 8MG COMPRIME)	1 COMPRIME PAR LA BOUCHE 2 FOIS PAR JOUR	2020/09/28	7	2021/[redacted]	10	16	
			FLURAZEPAM 30MG CAPSULE (FLURAZEPAM 30MG CAPSULE)	1 CAPSULE 1 FOIS PAR JOUR 1/2 HEURE AVANT COUCHER *PREPARER/ APPELER/ LIVRER*	2020/09/28	6	2021/[redacted]	10	30	
			LANCETTES LANCETTE (LANCETTES SOFTCLIX LANCETTE)	UTILISER CES LANCETTES AVEC VOTRE STYLO AUTOPIQUEUR	2020/10/30	999	2020/10/30	177	200 U	
			GLYCEMIE-TEST BANDELETTE (ACCU CHEK AVIVA BANDE BANDELETTE)	UTILISER LES BANDELETTES AVEC VOTRE GLUCOMÈTRE	2020/10/30	999	2020/10/30	177	100 U	

* L'information sur le délai permet d'identifier le laps de temps écoulé depuis la dernière délivrance. Cette information peut notamment permettre de repérer des médicaments qui sont actifs a[redacted]mais qui pourraient ne plus être pris par l'usager.

Ce document fait partie intégrante du dossier local de l'usager lorsqu'il y est consigné.
Dès lors, les règles de confidentialité et de conservation applicables à ce document sont celles prévues pour ce dossier local.

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ATIA - 19(1)

Dawson, Dianne (HC/SC)

From: Seguin, Michelle (HC/SC) on behalf of Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-05-26 1:35 PM
To: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Subject: FW: Suivi par Santé Canada - Vaccin COVID-19 AstraZeneca (Effets Secondaires)

Categories: Red Category, Michelle

From: Seguin, Michelle (HC/SC) **On Behalf Of** Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-05-26 12:21 PM
To: Eng, Kathleen (HC/SC) <kathleen.eng@canada.ca>; Lavigne, Andree-Anne (HC/SC) <andree-anne.lavigne@canada.ca>
Cc: Savaria, François (HC/SC) <francois.savaria@canada.ca>; Fraije, Jemma (HC/SC) <jemma.fraije@canada.ca>; Rose, Jhona (HC/SC) <jhona.rose@canada.ca>; Tam, Ron (HC/SC) <ron.tam@canada.ca>; Noble, Angela (HC/SC) <angela.noble@canada.ca>; Stothart, Tonja (HC/SC) <tonja.stothart@canada.ca>; Danoff, Deborah (HC/SC) <deborah.danoff@canada.ca>
Subject: FW: Suivi par Santé Canada - Vaccin COVID-19 AstraZeneca (Effets Secondaires)

Good afternoon,

Please find the follow up response below concerning AER#000947601.

Thank you,
Michelle

From: [redacted]
Sent: 2021-05-25 11:48 PM
To: Seguin, Michelle (HC/SC) <michelle.seguin@canada.ca>
Subject: Suivi vaccin covid astrazeneca NEI 000947601

Bonjour Mme Seguin,

Désolé du délai, votre fax semble avoir été transmis au mauvais endroit.

En réponse aux questions:

J'ai discuté avec la coroner [redacted] Le pathologiste aurait émis un rapport préliminaire qui montre un infactus transmural datant de [redacted] avant le décès (le vaccin a été reçu [redacted] avant le décès)

Il n'y a pas eu de prélèvement analysé au laboratoire de mon centre hospitalier autre qu'un test covid négatif. Les prélèvements ont été envoyé au laboratoire du coroner.

Je vous réfère au bureau du coroner pour les résultats d'autopsie et de prélèvement. Il ne semble pas avoir de lien finalement entre le vaccin et le décès de la patiente à ce que je peux comprendre.

Bien à vous

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ATIA - 19(1)

[redacted]

From: Seguin, Michelle (HC/SC) <michelle.seguin@canada.ca> **On Behalf Of** Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC)
Sent: 2021-04-28 8:43 AM
To: 18193723553@fax.hc-sc.gc.ca
Cc: Canada Vigilance COVID19 vaccine / vaccin COVID19 (HC/SC) <hc.canada.vigilance.COVID19vaccine-vaccinCOVID19.sc@canada.ca>
Subject: RE: Suivi par Santé Canada - Vaccin COVID-19 AstraZeneca (Effets Secondaires)

Dr [redacted]

Merci pour la déclaration d'un effet secondaire suivant l'immunisation (ESSI). Par conséquent de suivi d'évaluation par Santé Canada, le Programme de Canada Vigilance a identifié cette déclaration pour un suivi.

L'information que vous avez fournie dans votre déclaration a été enregistrée dans la base de données du Programme Canada Vigilance sous le numéro d'effet indésirable (NEI) 000947601.

Canada Vigilance N0	Clarification
000947601 (Date de réception [Santé Canada]): 26/04/2021	Veuillez SVP donnez toute information supplémentaire concernant: Informations cliniques concernant les antécédents médicaux actuels du patient, y compris tout facteur de risque cardiovasculaire potentiel (par exemple, diabète, antécédents de tabagisme, hypertension, hypercholestérolémie ou hyperlipidémie et antécédents de cardiopathies ischémiques). Si disponible, quel était le statut COVID-19 du patient au moment de l'effet indésirable. Informations sur le traitement médical et les investigations liées aux événements indésirables, par exemple, des analyses de sang (par exemple, numération globulaire complète et frottis sanguin, numération plaquettaire, D-dimère, taux d'anti-héparine) et examens radiologiques (par exemple, TDM, IRM, angiographie , échocardiogramme, etc.), si disponible. Résultat de l'enquête du coroner et de l'autopsie, si disponible.

Une réponse dans les meilleurs délais serait grandement apprécié pour l'évaluation de ce cas.

Si vous avez besoins de plus d'informations, n'hésitez pas à me contacter.

Merci de votre collaboration,

Michelle Séguin
Le Programme Canada Vigilance, Santé Canada

Michelle Séguin B.Sc., B.Sc.N., RN
Adverse Reaction Information Specialist / Spécialiste de l'information sur les effets indésirables
Marketed Health Products Directorate | Direction des produits de santé commercialisés
Health Products and Food Branch | Direction générale des produits de santé et des aliments

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A2023000085

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04559367 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20230505 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A684767()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210816 CCYYMMDD	20230504 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A684767

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC CANADA Market Authorization Holder AER Number AZPROD0000	000940311 [redacted] CA-AstraZeneca-2021A684767

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2)

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
			95 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04559367 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cardiac failure congestive
26.0	Dyspnoea

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intramuscular	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ELIGARD PRE-FILLED SYRINGES (3-MONTH) - SINGLE DOSE	
Active Substance names (B.4.k.2.2)		
leuprolide acetate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02248240 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms,1 every 3 (Months)		
Dosage text (B.4.k.6)		
POWDER FOR SUSPENSION, SUSTAINED RELEASE, 1 Every three months		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Prostate cancer Prostate cancer
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CARDIAC FAILURE CONGESTIVE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cardiac failure congestive		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Cardiac failure congestive		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSPNOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dyspnoea		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dyspnoea		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
No			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the Consumer via regulatory authority in Canada (CANADIAN HEALTH AUTHORITY), the report concerning a male patient of Unknown ethnic origin (age 95 years).

The patient's past and current medical history included cardiac failure congestive (dates not reported) and dyspnoea (dates not reported). No concomitant products were reported.

On an unknown date, the patient received Covishield Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadoxl ncov-19)) (batch number UNKNOWN), via intramuscular route, for covid-19 prophylaxis.

The patient started treatment with Eligard 22.5mg (leuprorelin acetate) (batch number(s) UNKNOWN) 1 DF every three months, subcutaneous, on an unknown date for prostate cancer and with Eligard 22.5mg (leuprorelin acetate) (batch number(s) UNKNOWN) 1 DF every three months, subcutaneous, on an unknown date for prostate cancer.

On an unknown date, the patient experienced cardiac failure congestive (preferred term: Cardiac failure congestive), dyspnoea (preferred term: Dyspnoea).

The patient died from the event of cardiac failure congestive and dyspnoea on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was cardiac failure congestive and dyspnoea.

The reporter assessed the events cardiac failure congestive and dyspnoea to be serious due to seriousness criteria of death.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

Summary of follow up information received by AstraZeneca on 16-AUG-2021 from regulatory authority (Canada) via consumer: Regulatory authority reference number was updated.

Summary of follow-up information received by AstraZeneca/MedImmune 04-May-2023 from consumer via spontaneous source: Duplicate case identified. Reporter case id associated. Event of DYSPNOEA outcome and seriousness criteria updated. Relevent history updated. Narrative amended.
CAUSE OF DEATH: CARDIAC FAILURE CONGESTIVE CAUSE OF DEATH: DYSPNOEA
COVISHIELD is a Verity Pharmaceuticals Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Fatal event of cardiac failure congestive is not listed in the company core data sheet of AZD1222. The event could be associated with the non-serious event dyspnoea. Age of patient could be a contributory risk factor for the event. Concomitant medication for prostate cancer could be a confounder for the event. The cause of death was reported as cardiac failure congestive and dyspnoea. Due to limited information regarding medical history of previous heart diseases, the onset date of the cardiac failure congestive and dyspnoea, date of vaccination, date of diagnosis of prostate cancer and start date of treatment, status of prostate cancer, date of death, circumstances leading to the event, cardiovascular risk factors (smoking, dyslipidemia, hypertension, diabetes), concurrent diseases, autopsy report details, diagnostic and etiological work-up (clinical and cardiovascular evaluation, blood chemistry profile, cardiac biomarkers, renal function, hepatic function, prostate-specific antigen test, electrocardiogram, chest x-ray, cardiac images), the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac failure congestive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Unknown	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cardiac failure congestive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyspnoea	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

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Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)
Pharmaceutical Company	AZPROD0000

Department (A.3.1.3a)	Title (A.3.1.3b)
Patient Safety	

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Patient Safety		Interface Organisation

Street (A.3.1.4a)
Pepparedsleden 1

City (A.3.1.4b)	State (A.3.1.4c)
Molndal	

Postcode (A.3.1.4d)	Country code (A.3.1.4e)
SE-431 83	United Kingdom

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)
317061000	317763796

Email Address (A.3.1.4l)
Sapphire.BusinessSupport@astrazeneca.com

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Receiver (A.3.2)

Type (A.3.2.1) Regulatory Authority		**Organization** (A.3.2.2a) MHPD
Department (A.3.2.2b) Trading Partner Management Office		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a) 250 Lanark Avenue, Mail Stop 2005A		
City (A.3.2.3b) Ottawa		**State** (A.3.2.3c) ON
Postcode (A.3.2.3d) K1A 0K9		**Country** (A.3.2.3e) Canada
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l) TPMO_BGPC@hc-sc.gc.ca		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04561608 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211001 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101029604(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
2021[redacted] CCYYMMDD	20210925 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101029604

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101029604

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) E2B_04843733

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			29 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04561608 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 2 (INITIAL PFIZER DOSE), SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
		1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cancer	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyslexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dyslexia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Heart attack	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Interchange of vaccine products	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Interchange of vaccine products	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label use	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Off label use	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Psychiatric disorder NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Psychiatric disorder NOS	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retardation mental	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retardation mental	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal detachment	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal detachment	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal tear	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal tear	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal thinning	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Retinal thinning	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEART ATTACK

MedDRA version for reaction/event term LLT (B.2.i.1.a)	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b)		
26.0	Heart attack		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Myocardial infarction		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

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Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETINA TEAR

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Retinal tear		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Retinal tear		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETINA DETACHMENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Retinal detachment		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Retinal detachment		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ALL DSM 5

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Psychiatric disorder NOS		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Mental disorder		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETARDATION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Retardation mental		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Intellectual disability		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cancer		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Neoplasm malignant		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RETINA THINNING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Retinal thinning
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Retinal degeneration

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSLEXIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Dyslexia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Dyslexia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERCHANGE OF VACCINE PRODUCTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Off label use
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Off label use

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERCHANGE OF VACCINE PRODUCTS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Interchange of vaccine products
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Interchange of vaccine products

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04561608 (1)	Page#7

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received via COVAES from contactable consumers (patient's parents) 29-year-old contactable male (patient) regarding Pfizer product Pfizer-BioNTech COVID-19 vaccine (BNT162b2) the following was reported.

A 29-years-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on [redacted]021 (Batch/Lot Number: Unknown) as DOSE 2 (INITIAL PFIZER DOSE), SINGLE for covid-19 immunization, at the age at vaccination of 29 years. Medical history included ECT (electroconvulsive therapy) from 10Mar2020 (Duration of Hospitalization: 4. Hospitalization prolonged: yes. Treatment Received: unknown), Meningitis acwy from May2018 (Hospitalization Prolonged: Yes. Treatment received: No), whole dsm5 (diagnostic and statistical manual of mental disorders). The patient's concomitant medications were not reported. Historical vaccine included first dose of Moderna (Batch/Lot number: not available) on [redacted]2021 (also reported as [redacted]2021, pending confirm). The patient experienced retina tear- retina detachment-heart attack-all dsm (diagnostic and statistical manual of mental disorders) 5-dyslexia-retardation-cancer-retina thinning, all on unknown date. Treatment received was unknown. The event heart attack with seriousness criteria of death, hospitalization, medically significant with fatal outcome, other events with seriousness criteria of medically significant with outcome of unknown. The adverse events result in: Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Patient also experienced interchange of vaccine products on an unspecified date with outcome of unknown. The patient died on [redacted]2021. It was not reported if an autopsy was performed. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, unknown if the patient been tested for COVID-19.

The lot number for BNT162b2 was not provided and will be requested during follow up.

Follow-up (25Sep2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	ECT	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
20200310 CCYYMMDD		
Comments (B.1.7.1g)		
Duration of Hospitalization: 4. Hospitalization prolonged: yes. Treatment Received: unknown.		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Meningitis meningococcal	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
201805 CCYYMM		
Comments (B.1.7.1g)		
Hospitalization Prolonged: Yes. Treatment received: No.		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Mental disorder NOS	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		
diagnostic and statistical manual of mental disorders		

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Canada Vigilance AER#:	E2B_04561608 (1)	Page#8

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

MODERNA COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04561608 (1)	Page#9

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04565536 (2)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220301 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A684773()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210816 CCYYMMDD	20220223 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
No	
	Company number (A.1.10.2)
	CA-AstraZeneca-2021A684773

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
CANADIAN HEALTH AUTHORITY MC Canada AZPROD0000	000943098 [redacted] CA-AstraZeneca-2021A684773

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			85 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04565536 (2)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Disease progression
26.0	Dizziness
26.0	Fall
26.0	Malaise
26.0	Prostate cancer

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVISHIELD VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02512947 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ELIGARD PRE-FILLED SYRINGES (4-MONTH) - SINGLE DOSE	
Active Substance names (B.4.k.2.2)		
leuprolide acetate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02248999 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
30 MG, 1 every 4 months		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Subcutaneous	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0 26.0	Prostate cancer Prostate cancer
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fall		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Fall		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

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No			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)		Outcome (B.2.i.8) Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PROSTATE CANCER

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Prostate cancer		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Prostate cancer		
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)		Outcome (B.2.i.8) Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DISEASE PROGRESSION

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Disease progression		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Disease progression		
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)		Outcome (B.2.i.8) Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIZZINESS

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Dizziness		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Dizziness		
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)		Outcome (B.2.i.8) Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MALAISE

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Malaise		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Malaise		
Term hightlighted by the reporter? (B.2.i.3) No	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)		Outcome (B.2.i.8) Fatal

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Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from Health Professional via regulatory authority in Canada (Canadian Health Authority), concerning a male patient of Unknown ethnic origin (age 85 years).

No medical history and No concomitant products were reported.

On an unknown date, patient received Covishield Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)), via intramuscular route, for covid-19 prophylaxis.

On an unknown date, patient started treatment with Eligard 30mg (leuprorelin acetate) 30 MG, 1 every 4 months , subcutaneous, for prostate cancer. On an unknown date patient started treatment with with Eligard 30mg (leuprorelin acetate) 30 MG, 1 every 4 months, subcutaneous, for prostate cancer.

On an unknown date, the patient experienced fall (preferred term: Fall), prostate cancer (preferred term: Prostate cancer), disease progression (preferred term: Disease progression), dizziness (preferred term: Dizziness) and malaise (preferred term: Malaise).

It was unknown if any action was taken with Covishield Vial Contains 10 Doses Of 0.5ml and both the doses of Eligard 30mg

On an unspecified date, patient died from the event of fall, prostate cancer, disease progression, dizziness and malaise

The cause of death was fall, prostate cancer, disease progression, dizziness and malaise.

The reporter assessed the events of fall, prostate cancer, disease progression, dizziness and malaise as serious due to seriousness criteria of death

Summary of follow-up information received by AstraZeneca/MedImmune on 16-AUG-2021 From Regulatory authority via consumer and Reporter ID of Regulatory Authority was added.

Summary of follow up information received by AstraZeneca/MedImmune on 23-Feb-2022 from Health Professional via Spontaneous source. New reporter Health Professional was added. New events Disease Progression, Prostate Cancer added.Narrative amendedCAUSE OF DEATH: FALL CAUSE OF DEATH: PROSTATE CANCER CAUSE OF DEATH: DISEASE PROGRESSION CAUSE OF DEATH: DIZZINESS CAUSE OF DEATH: MALAISE FALL - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PROSTATE CANCER - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DISEASE PROGRESSION - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes DIZZINESS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes MALAISE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes
COVISHIELD is a Verity Pharmaceuticals Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal events of fall, prostate cancer, disease progression, dizziness and malaise are not listed in company core data sheet of AZD1222. The cause of death was reported as fall, prostate cancer, disease progression, dizziness and malaise. Prostate cancer and disease progression could be in association with each other and contributory to fall, dizziness and malaise. Vaccinee's history of prostate cancer could be considered as contributory factor to the events. Vaccinee's concomitant use of leuprorelin acetate could be considered as a confounding factor to the events. Due to limited information on risk factors, circumstances surrounding the events, date of the vaccination, onset date of the events, date of death, therapeutic measures taken with respect to the events, relevant family history, other concomitant medications, autopsy details if performed, detailed etiological and diagnostic work-up (complete blood analysis, general physical examination, radiology imaging studies), the evaluattion did not find evidence to suggest a causal relationship between the events and AZD1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fall	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Prostate cancer	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Disease progression	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dizziness	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Malaise	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

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Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date** (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	**Indication** (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	**Reactions** (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	UNKNOWN	UNKNOWN	UNKNOWN

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04566093 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date: 20210906 CCYYMMDD	
	HC Initial Received Date: 2021 CCYY	

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-AstraZeneca-2021A684801()

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20210816 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20210816 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) No	**Regulatory authority's number (A.1.10.1)**
	Company number (A.1.10.2) CA-AstraZeneca-2021A684801

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1) CANADIAN HEALTH AUTHORITY MC CANADA AZPROD0000	**Duplicate Case identifiers (A.1.11.2)** 000944395 [redacted] CA-AstraZeneca-2021A684801

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - ASTRAZENECA

Patient (B.1)

Patient Initial (B.1.1) UNKNOWN	**Sex (B.1.5)** Female	**Patient height (B.1.4)**	**Patient weight (B.1.3)**
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebrovascular accident

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COVISHIELD VIAL CONTAINS 10 DOSES OF 0.5ML	
Active Substance names (B.4.k.2.2)		
chadox1-s [recombinant]		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	UNKNOWN	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02512947 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Dose Unknown ONCE/SINGLE ADMINISTRATION		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intramuscular	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CEREBROVASCULAR ACCIDENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cerebrovascular accident
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cerebrovascular accident

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

A spontaneous report has been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via Consumer concerning a female patient (age not provided) of Unknown ethnic origin.

No medical history and no concomitant products were reported.

The patient received Covishield Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml (covid-19 vaccine nrvv ad (chadox1 ncov-19)) (batch number UNKNOWN) once/single administration, via intramuscular route, on an unknown date. On an unknown date, the patient experienced cerebrovascular accident (preferred term: Cerebrovascular accident).

The action taken for Covishield Covid-19 Vaccine Vial Contains 10 Doses Of 0.5ml in response to the event cerebrovascular accident was not applicable. The patient died from the event cerebrovascular accident on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was cerebrovascular accident.

The event cerebrovascular accident was considered serious by the reporter due to seriousness criteria death.

For regulatory reporting purposes, if an event is spontaneously reported, at least a reasonable possibility of a causal relationship is implied by the reporter, even if the relationship is unknown or unstated.

The AstraZeneca COVID-19 Vaccine is an AstraZeneca Canada Inc. product authorized under the Interim Order.

Summary of follow-up information received by AstraZeneca on 16-AUG-2021: A spontaneous report had been received from the regulatory authority in Canada (CANADIAN HEALTH AUTHORITY) via Consumer and new information was added.
The regulatory authority Reference number was incorporated in the Reporter's Case ID field.
CAUSE OF DEATH: CEREBROVASCULAR ACCIDENT
COVISHIELD is a Verity Pharmaceuticals Inc. product authorized under the Interim Order.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Fatal event of cerebrovascular accident is not listed in the company core data sheet of AZD 1222. The reported cause of the death was cerebrovascular accident (PT: cerebrovascular accident).
Due to the limited information on patient's baseline health status, patient demographic information, medical history, family history, concurrent diseases, concomitant medications, risk factors, autopsy report, exact onset date of the event, diagnostic and etiological work-up (such as complete laboratory workup, imaging techniques, neurological evaluation and exams), further clarification of the event, clinical course and treatment details, the evaluation did not find evidence to suggest a causal relationship between the event and AZD 1222.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebrovascular accident	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY	UNKNOWN	CANADIAN HEALTH AUTHORITY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)
UNKNOWN

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
UNKNOWN	UNKNOWN

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
UNKNOWN	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			Confidential

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04571440 (3)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220203 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101022572(4)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210809 CCYYMMDD	20220124 CCYYMMDD	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101022572

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101022572

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			89 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04571440 (3)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	No

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Bacteraemia
26.0	Endocarditis infective
26.0	Urosepsis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EL0203	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunization
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2021[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
6534 Minutes	6534 Minutes	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

Document Released Under the Access to Information Act by Health Canada / Document divulgué en vertu de la Loi sur l'accès à l'information par Santé Canada

26.0	Bacteraemia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Bacteraemia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cardiorenal syndrome	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cardiorenal syndrome	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dementia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Dementia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Endocarditis infective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Endocarditis infective	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hypernatremia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hypernatremia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pleural effusion	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pleural effusion	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Respiratory distress	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Respiratory distress	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Urosepsis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Urosepsis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) TECTA	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 40 Milligram		
Dosage text (B.4.k.6) 40 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) GERD
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	DONEZEPIL ACCORD	
Active Substance names (B.4.k.2.2)		
DONEPEZIL HYDROCHLORIDE		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
10 Milligram		
Dosage text (B.4.k.6)		
10 mg		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Dementia
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN D3	
Active Substance names (B.4.k.2.2)		
vitamin d3		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1000 IU (International Unit),1 every 1 (Days)		
Dosage text (B.4.k.6)		
1000 iU, 1x/day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Bone disorder
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ELTROXIN	
Active Substance names (B.4.k.2.2)		
levothyroxine sodium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
100 Microgram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
100 ug, 1x/day		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Hypothyroidism
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) CYANOCOBALAMIN	
Active Substance names (B.4.k.2.2) vitamin b12		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 1000 Microgram,1 every 1 (Days)		
Dosage text (B.4.k.6) 1000 ug, 1x/day		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Sublingual	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) Vitamin B12 deficiency
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ESTRING	
Active Substance names (B.4.k.2.2) estradiol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02168898 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 2 Milligram,1 every 3 (Months)		
Dosage text (B.4.k.6) 2 mg, every 3 months		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Vaginal	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** SYMBICORT TURBUHALER	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK, 2x/day (200, 2 puffs inhaled)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VENTOLIN HFA	
Active Substance names (B.4.k.2.2)		
salbutamol		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02241497 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
100 Microgram,6 every 1 (Days)		
Dosage text (B.4.k.6)		
100 ug, every 4 hrs (100 mcg, 1 puff, PRN)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIAGNOSED WITH UROSEPSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Urosepsis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Urosepsis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
6534 Minutes	6534 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BACTERAEMIA

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Bacteraemia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Bacteraemia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
5 Days	5 Days	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INFECTIVE ENDOCARDITIS.

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Endocarditis infective
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Endocarditis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
6534 Minutes	6534 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CARDIORENAL SYNDROME GIVEN THE WORSENING PULMONARY EDEMA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cardiorenal syndrome
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Cardiorenal syndrome

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
6534 Minutes	6534 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RESPIRATORY DISTRESS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Respiratory distress
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Respiratory distress

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
6534 Minutes	6534 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ACUTE HYPERNATREMIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Hypernatremia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Hypernatraemia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

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6534 Minutes	6534 Minutes	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

RAPID PROGRESSION OF HER DEMENTIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Dementia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Dementia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
6534 Minutes	6534 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PLEURAL EFFUSIONS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Pleural effusion		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pleural effusion		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2021[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
6534 Minutes	6534 Minutes	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug allergy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Drug hypersensitivity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Allergy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hypersensitivity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Allergy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Hypersensitivity

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report from two contactable consumers (one consumer was reported as "patient") and a physician.
A 89 year-old female patient (not pregnant) received bnt162b2 (COMIRNATY), administered in arm left, administration date [redacted]2021 11:06 (Lot number: EL0203) at the age of 89 years as dose 1, single for covid-19 immunisation. Relevant medical history included: "Hypothyroid" (ongoing); "severe Alzheimer's dementia", start date: 2015 (ongoing), notes: Progressive worsening since 2015, most recent MMSE thought to be 13-15, baseline GCS approximately 14-15, urinary and fecal incontinence at baseline, on Donepezil; "mixed urinary incontinence" (unspecified if ongoing); "liable of COPD" (ongoing), notes: Patient was never a smoker so the diagnosis is very much in doubt.; "Osteoarthritis" (ongoing); "Dyslipidemia" (unspecified if ongoing); "mixed stress and urge incontinence" (unspecified if ongoing); "mixed stress and urge incontinence" (unspecified if ongoing); "Nephrolithiasis" (unspecified if ongoing); "Osteoporosis" (unspecified if ongoing); "Vitamin b12 deficiency" (not ongoing), notes: maintenance; "Appendectomy", start date: 1960 (unspecified if ongoing); "Cataract extraction", start date: 2011 (unspecified if ongoing), notes: right; "Cataract extraction", start date: 2012 (unspecified if ongoing), notes: left; "Cholecystectomy", start date: 1965 (unspecified if ongoing); "Total abdominal hysterectomy", start date: 1969 (unspecified if ongoing), notes: with unilateral salpingo-oophorectomy; "Total hip arthroplasty", start date: 2003 (unspecified if ongoing), notes: left, In the setting of a motor vehicle accident; "significant UTI" (unspecified if ongoing), notes: requiring hospitalization; "Breast biopsies" (unspecified if ongoing); "Hysterectomy" (unspecified if ongoing); "GERD" (unspecified if ongoing); "bone health" (unspecified if ongoing). Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication(s) included: TECTA taken for gastrooesophageal reflux disease (ongoing); DONEZEPIL ACCORD taken for dementia (ongoing); VITAMIN D 3 taken for bone disorder (ongoing); ELTROXIN taken for hypothyroidism (ongoing); VITAMIN B12 NOS taken for vitamin b12 deficiency (ongoing); ESTRING; SYMBICORT TURBUHALER; VENTOLIN HFA. Past drug history included: Codeine, reaction(s): "Known allergies", notes: Gastrointestinal upset in response to Codeine; Clavulin, reaction(s): "Allergy"; Penicillin, reaction(s): "allergy", notes: Label on patient's chart. She has however reportedly had penicillin, amoxicillin and other beta-lactams in the past with no reaction, according to her daughter. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine, but received other medications the patient within 2 weeks of vaccination. Past drug history included known allergies with codeine. Patient experienced onset of vomiting on [redacted]2021, then low-grade fever, rapid heart rate, rapid breathing pattern, steady decline in health, eventually leading to hospitalization on [redacted]021, for duration of 13 days. Patient was diagnosed with urosepsis, bacteraemia and eventually infective endocarditis, cardiorenal syndrome given the worsening pulmonary edema, Acute hypernatremia, respiratory distress. pleural effusions, rapid progression of her dementia with onset [redacted]021 (death, hospitalization, medically significant, life threatening). The patient was hospitalized for urosepsis, bacteraemia, endocarditis (start date: [redacted]2021, discharge date: [redacted]2021, hospitalization duration: 12 day(s)). Treatment received included IV treatment and cardiac care. The adverse event result in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. No hospitalization prolonged applied. The patient underwent the following laboratory tests and procedures: alanine aminotransferase: [redacted]021) 108, notes: Elevated; [redacted]021) 145, notes: High; anion gap: [redacted]021) 12; aspartate aminotransferase: [redacted]2021) 71, notes: High; blood albumin: [redacted]2021) 30, notes: Low; blood alkaline phosphatase: [redacted]2021) 88; blood bicarbonate: [redacted]021) 85; blood bilirubin: [redacted]2021) 8; blood calcium: [redacted]2021) 2.23; blood chloride: [redacted]2021) 98; blood creatine phosphokinase: [redacted]021) 17; blood creatinine: [redacted]021) 76; [redacted]021) 138; blood culture: [redacted]021) positive for aerococcus urinae (aa), notes: also reported as gram-positive cocci and Aerococcus bacteremia; blood lactic acid: [redacted]021) 3.0, notes: elevated; [redacted]021) 1.9; blood magnesium: [redacted]2021) 0.82; blood phosphorus: [redacted]2021) 1.03; blood potassium: [redacted]2021) 3.3, notes: hypokalemia; [redacted]021) 4.1; blood pressure measurement: [redacted]2021) 120/68 mmHg; [redacted]2021) 155/50 mmHg; blood sodium: [redacted]2021) 133, notes: mild hyponatremia; [redacted]021) 139; [redacted]021) 147; [redacted]2021) 150, notes: from 146 (unspecified date); blood thyroid stimulating hormone: [redacted]2021) 1.94; body temperature: [redacted]2021) 37 Centigrade; brain natriuretic peptide: [redacted]2021) 1.498; carbon dioxide: [redacted]2021) 30; chest x-ray: [redacted]021) normal; [redacted]021) pleural effusions, notes: with slight worsening of right basilar atelectasis; [redacted]2021) deterioration, notes: with worsening interstitial pulmonary edema, mostly on the left lower and upper zone; computerised tomogram head: [redacted]2021) no acute intracranial abnormality, notes: Generalized atrophy noted; c-reactive protein: [redacted]2021) 173, notes: High; [redacted]021) elevated; echocardiogram: [redacted]021) severe pulmonary hypertension, notes: with RVSP at 75 with moderate mitral regurgitation and moderate aortic regurgitation; ejection fraction: [redacted]021) 55 %; electrocardiogram: [redacted]021) did not show any acute st segment changes, notes: she was in sinus rhythm; [redacted]021) sinus tachycardia with anterior t wave inversions, notes: Not new compared to the previous ECGs; glomerular filtration rate: [redacted]021) 60; [redacted]021) 29, notes: dropping from 46 (unspecified date); haematocrit: [redacted]021) 0.37; haemoglobin: [redacted]2021) 119; [redacted]021) 121; [redacted]021) 102; heart rate: (unspecified date) rapid; [redacted]2021) 98; [redacted]021) 100-110, notes: bpm; lymphocyte count: [redacted]021) 1.0; mean cell volume: [redacted]021) 94; neutrophil count: [redacted]021) 15.3; [redacted]021) 13.5, notes: High; oxygen saturation: [redacted]2021) 99 %; [redacted]021) 98 %, notes: on 1L O2; pco2: [redacted]2021) 50; ph body fluid: [redacted]021) 7.49; [redacted]021) 7.46; platelet count: [redacted]2021) 260; red cell distribution width: [redacted]021) 13.6; respiratory rate: (unspecified date) rapid; [redacted]021) 42, notes: did not look to be in any distress; [redacted]021) 20s; sars-cov-2 test: [redacted]021) negative; [redacted]021) negative; [redacted]021) negative; [redacted]021) negative; troponin: [redacted]021) 0.19; [redacted]021) 0.16, notes: High; urine analysis: [redacted]2021) positive for entococcus faecalis, notes: >= 1x10E7 CFU/L no pyuria. Unless there is a clinical diagnosis of UTI (e.g. dysuria, frequency, or non-localizing symptoms/signs e.g. fever, sepsis with NO other cause), this result most often represents asymptomatic bacteriuria (ASB), antibiotics are NOT indicated for ASB EX CEPT during pregnancy or prior to any urological procedure likely to cause mucosal bleeding. Changes in mental status or character of urine WITHOUT localizing urinary symptoms are NOT diagnostic of UTI; white blood cell count: [redacted]021) 17.6; [redacted]2021) 16.3, notes: High; [redacted]021) 9.1. Therapeutic measures were taken as a result of urosepsis, bacteraemia, endocarditis. The patient date of death was [redacted]2021. The reported cause of death was urosepsis, bacteraemia, endocarditis. No autopsy was performed. Patient died on [redacted]2021. Outcome of the events was fatal.

Additional information:
Medical profile [redacted]021) Patient in intensive care unit (CCU) from [redacted]2021 to [redacted]2021. Treated with Fosfomycin, Ceftriaxone and PIP Tazo. Consult note dated [redacted]2021: Patient presenting with altered level of

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consciousness and dyspnea, found to have a marked leukocytosis, elevated CRP, tachycardia/tachypnea and blood cultures positive for Aerococcus, consistent with a diagnosis of urosepsis. Reason for referral: urosepsis. Social history: For the past years, patient has been living in the facility (name redacted), owing to her advanced dementia. According to her daughter, she is able to walk approximately half a block unassisted and will provide short verbal answers to questions. She is able to understand and obey commands. History of presenting illness: Transferred from ospital (name redacted)with a presumed diagnosis of urosepsis and possibly congestive heart failure. The patient is currently nonverbal so much of what follows is collateral history provided both by the transfer documents as well as the patient's daughter. Apparently, the patient was essentially well until receiving her COVID-19 vaccine on [redacted]2021. In the week following this vaccination, the patient developed symptoms of nausea and vomiting, resulting in a period of isolation at her facility. Following this isolation, she was found to not be at her functional baseline, both physically and cognitively. Her family suspected that she was developing a urinary tract infection as of approximately 10 days ago. With her previous urinary tract infections, the patient has had very similar symptoms. She was initially investigated as an outpatient with a urinalysis on [redacted] which revealed no pyuria but urine culture positive for Enterococcus faecalis. She was subsequently started on treatment with fosfomycin on [redacted]021. Due to worsening symptoms, she was subsequently transferred to hospital on [redacted]2021 where she was initially treated with ciprofloxacin. No repeat urine culture was sent, but blood cultures were positive for Aerococcus urinae. She was subsequently started on ceftriaxone for her Aerococcus bacteremia. In hospital, the patient was noted to be continuously tachypneic and dyspneic, despite requiring no oxygen. Given an elevated BNP and bilateral pleural effusions, she was felt to be in decompensated heart failure and was started on furosemide 40 mg IV daily from [redacted] until [redacted]2021. She received a 4-day course of empiric prednisone therapy for query acute exacerbation of COPD between [redacted]2021 and [redacted]2021. This was discontinued, as it was felt that the bulk of her symptoms were more consistent with heart failure. Given her clinical deterioration and rising white blood cell count, she was transferred to the Hospital (name redacted) on [redacted]021 2021. Here she was noted to have had an abrupt decrease in her level of consciousness to approximately 11 from a baseline of approximately 14-15 in facility name redacted. Physician spoke with patient's daughter who confirmed that her goals of care are M1. She works as a nurse and is very aware of how potentially serious this prognosis is. As an interesting aside, physician asked the patient's daughter about the patient's previous smoking history in light of her diagnosis of COPD. Her daughter replied that the patient never smoked. In terms of any lung problems, the patient's daughter reported that the patient used to routinely go down to vacation in Arizona and that she frequently returned with a harsh, barky cough that the patient referred to as "valley fever". Physician does not feel that this is relevant to her current presentation, but does wonder about a history of histoplasmosis or blastomycosis that may be worth investigating.

O[redacted]2021: Afebrile, looks unwell, moaning continuously. Neuro: GCS 11-12, obeys some but not all commands, PERL. HEENT: Non-contributory. CVS: Normal S1S2, no EHS/murmurs audible in ED, JVP below the clavicle by ultrasound. Resp: Clear, decreased air entry to the bases. Abdomen: Soft and non-tender. GU: Non-contributory. Extremities: Warm and dry, no peripheral edema. Skin: Warm and dry. Impression: Overall, her presentation seems to be most in keeping with urosepsis plus or minus decompensated heart failure on a background of overall poor function.
Issues and plan: 1) Urosepsis with Aerococcus bacteremia:
-Etiology: Given her past history of recurrent UTIs and the similarity of her current presentation to those episodes, urosepsis appears to be the most likely diagnosis at this period.
It is interesting that her urine culture grew Enterococcus faecalis whereas her blood grew Aerococcus urinae, however physician thinks it would be reasonable to treat both organisms at this point.
-Investigations: We have repeated her blood cultures, urinalysis, and urine cultures. We have repeated her Covid swab due to her ongoing dyspnea. We have ordered a repeat CRP.
-Management: We will change the patient's antibiotics from ceftriaxone to piperacillin-tazobactam 3.375 g IV every 6 hours. She will need a 14-day course following the onset of her bacteremia.
Given the patient's flat JVP and ongoing tachycardia, we will provide a 500 mL bolus of Ringer's lactate and will run a Ringer's lactate infusion at 50 mL/h for 10 hours. Her volume status will need to be reassessed in light of the concerns of ongoing heart failure.
2) Query decompensated heart failure:
-Etiology: Patient has no previous history of heart failure. Her BNP is certainly markedly elevated, but her pleural effusions may be of alternate etiologies. She has no peripheral edema. Repeated x-rays have not demonstrated pulmonary edema.
-Investigations: We will arrange for the patient to have a transthoracic echocardiogram while in hospital. Given the patient's tachypnea, tachycardia, and pleural effusions of unclear origin, we will order a CT PE to rule out pulmonary embolism as a cause of her ongoing presentation and to further evaluate these pleural effusions.
-Management: We will not diurese the patient any further at this time owing to the fact that she appears clinically dry, that she is developing a metabolic alkalosis, and that she is currently septic. We will start the patient on a low-sodium diet and will monitor her weights daily. We will gently fluid resuscitate the patient in light of the possibility of heart failure. We will follow-up on the results of the CT PE and manage accordingly.
3) Normocytic anemia:
-Etiology: Very mild anemia overall, most likely etiologies being anemia of chronic disease and iron deficiency anemia.
-Investigations: We have ordered a preliminary work-up including iron studies, ferritin, B12, folate, TSH, peripheral blood smear, and liver enzymes.
-Management: We will follow up on the aforementioned work-up and arrange management accordingly.
4) Altered level of consciousness:
-Etiology: The patient's level of consciousness reportedly fell from 15 to 11 over the course of the day. Though ongoing sepsis superimposed on pre-existing dementia is the most likely cause of her symptoms, all of the usual DIMS etiologies apply.
-Investigations: All of the basic DIMS work-up has been sent, including septic work-up, metabolic studies, and a CT of the patient's head. She is on no offending medications of note. CT head did not reveal any acute intracranial abnormality. The rest of her work-up is currently pending.
-Management: We will follow-up on these investigations and will manage accordingly.
5) Transaminitis:
-Etiology: Unclear etiology at present time, but has worsened since her initial admission to hospital on [redacted]2021.
-Investigations: We will obtain an ultrasound of the patient's abdomen to look for any evidence of hepatic abscess or other structural lesions that may be causing the patient's pattern of hepatocellular transaminitis. We have not sent off the full transaminitis work-up at this point as viral, metabolic, and autoimmune etiologies would seem to be far less likely. We will consider additional work-up should the patient's transaminitis persist without a clear etiology.
-Management: We will continue to monitor her liver enzymes daily for the next 3 days and will follow up on her abdominal ultrasound.
6) Troponitis:

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-Etiology: Likely demand ischemia in the context of ongoing sepsis plus or minus heart failure. No complaints of chest pain and no apparent ECG changes from previous.
-Investigations: Repeat troponin in 3 hours time.
-Management: Follow-up on this repeat troponin, with response depending on the amount of elevation.
7) Chronic conditions:
Management: Dementia: Continue on home donepezil. We will consult PT/OT/SLP to assess the patient's overall function and see if any optimization can be made. SLP in particular will be consulted to see if there is any risk of aspiration in light of the patient's severe dementia. Hypothyroidism: Continue on home levothyroxine. COPD: Continue on home puffers.
8)Standards of care: VTE prophylaxis: Tinzaparin. Nutrition: Heart healthy diet. Disposition: From redacted facility, with a baseline GCS of approximately 14-15. Goals of care: M1.

Discharge summary: Admit date: [redacted]021, discharge date: [redacted]021.
Discharge diagnosis: Urosepsis with urine culture growing Enterococcus faecalis susceptible to ampicillin, complicated by bacteremia with blood culture demonstrating Aerococcus urinae susceptible generally to penicillin.
Patient transferred to hospital to treat the following issues:
1. Urosepsis: This patient has a history of recurrent UTI and urine culture grew Enterococcus faecalis, currently on PIP Tazo.
2. Bacteremia growing aerococcus urinae that is susceptible to Penicillin, currently on PIP Tazo.
3. Nutrition: SLP assessment was done, and she is at high risk of aspiration. She was previously on modified diet, but for now we will keep her n.p.o. and gentle normal saline IV infusion at 50 mL/h while waiting SLP recommendation.
4. Asymmetrical pulmonary edema: This seems cardiogenic in nature with BNP at 1498. Of note, no evidence of previous ischemic heart disease or heart failure. Radio imaging with chest x-ray initially shows moderate size left- sided pleural effusion and small right pleural effusion, but on [redacted] it seems her imaging showing deterioration with worsening interstitial pulmonary edema, mostly on the left lower and upper zone. Echocardiogram was done on [redacted] showing severe pulmonary hypertension with a RVSP at 75 with moderate mitral regurgitation and moderate aortic regurgitation, however, ejection fraction was at 55%. This could be diastolic dysfunction although there is no mentioning of this in echocardiogram report. Currently, she is on Lasix 20 mg IV b.i.d. and her 02 supply remained steady at 1.5 to 2L nasal cannula. Her GCS is difficult to interpret, although she is alert with eye opening. Other vital signs are within acceptable range. Goals of care: At this point, her goals of care is M1. We had a conversation with the daughter about switching goals of care to comfort level given the overall picture as pulmonary edema is worsening, and it would be wise to switch her to C1. It seems the family fully understood the situation and the daughter will be phoning the brother to make the final decision.
Discharge summary: Infectious disease team was consulted as echocardiogram shows a possible vegetation while transesophageal echocardiogram is optimal to pinpoint whether there is vegetation or not. Given the age of the patient and the complex picture, this transesophageal echocardiogram may not be feasible upon Cardiology team impression. ID decided to stop ampicillin temporarily and switch to piperacillin and tazobactam because the aerococcus bacteremia could increase risk of Infective endocarditis. We had a lengthy conversation with ID team, and we felt that we will continue the piperacillin and tazobactam for 5 days before switching back to ampicillin on [redacted] for 6 weeks and treating the bacteremia and urosepsis. New issues: New AKI with creatinine of 138 and GFR 29, dropping from 46. It seems to me this is more of cardiorenal syndrome given the worsenin

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The events of Urosepsis, bacteraemia ,Cardiorenal syndrome, Respiratory distress, Hypernatremia, pleural effusion and Endocarditis are assessed as possibly related to the suspect drugBNT162B2 based on temporal association, but consider also possible contributory effects from patient's medical history and/or concomitant medications
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	COVID-19 virus test	Negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	COVID-19 virus test	Negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Urinalysis	positive for Entococcus faecalis	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	

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2021[redacted] CCYYMMDD	Absolute neutrophil count	15.3	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Alanine aminotransferase	108	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Albumin	30	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Blood culture	positive for Aerococcus urinae (AA)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Blood pressure	120/68	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
mmHg			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Body temperature	37	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
Centigrade			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Chest X-ray	Normal	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	COVID-19 virus test	Negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	ECG	did not show any acute ST segment changes	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Heart rate	98	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Hemoglobin	119	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	K	3.3	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Lactate	3.0	

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Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Oxygen saturation	99	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
%			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	pH	7.49	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Respiratory rate	42	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Sodium	133	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Troponin	0.19	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	TSH	1.94	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	WBC	17.6	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Troponin	0.16	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	C-reactive protein	173	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Chest X-ray	Pleural effusions	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Absolute lymphocyte count	1.0	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Absolute neutrophil count	13.5	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

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			Yes
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Alanine aminotransferase	**Test result** (B.3.1d) 145	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) Yes
Test date (B.3.1b) 202[redacted] CCYYMMDD	**Test name** (B.3.1c) Alk phos	**Test result** (B.3.1d) 88	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Anion gap	**Test result** (B.3.1d) 12	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Aspartate aminotransferase	**Test result** (B.3.1d) 71	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) Yes
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Bicarbonate	**Test result** (B.3.1d) 85	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Bilirubin	**Test result** (B.3.1d) 8	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 202[redacted] CCYYMMDD	**Test name** (B.3.1c) Blood pressure	**Test result** (B.3.1d) 155/50	
Unit (B.3.1e) mmHg	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) BNP	**Test result** (B.3.1d) 1,498	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 2021[redacted] CCYYMMDD	**Test name** (B.3.1c) Calcium	**Test result** (B.3.1d) 2.23	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 202[redacted] CCYYMMDD	**Test name** (B.3.1c) CK	**Test result** (B.3.1d) 17	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 202[redacted] CCYYMMDD	**Test name** (B.3.1c) Cl	**Test result** (B.3.1d) 98	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b) 202[redacted] CCYYMMDD	**Test name** (B.3.1c) CO2	**Test result** (B.3.1d) 30	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No

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Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	COVID-19 virus test	Negative	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	C-reactive protein	elevated	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Creatinine	76	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	ECG	Sinus tachycardia with anterior T wave inversions	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Estimated glomerular filtration rate	60	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Head CT	No acute intracranial abnormality	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Heart rate	100-110	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Hematocrit	0.37	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Hemoglobin	121	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	K	4.1	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Lactate	1.9	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Magnesium	0.82	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3) No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	

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2021[redacted] CCYYMMDD	MCV	94	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Oxygen saturation	98	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
%			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	PCO2	50	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
202[redacted] CCYYMMDD	pH	7.46	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Phosphate	1.03	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Platelet count	260	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
202[redacted] CCYYMMDD	Red cell distribution width	13.6	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Respiratory rate	20s	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Sodium	139	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	WBC	16.3	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Echocardiogram	severe pulmonary hypertension	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
2021[redacted] CCYYMMDD	Ejection fraction	55	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
%			No
Test date (B.3.1b)	**Test name** (B.3.1c)	**Test result** (B.3.1d)	
202[redacted] CCYYMMDD	Sodium	147	

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Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
202[redacted] CCYYMMDD	Chest X-ray	deterioration	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Creatinine	138	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Estimated glomerular filtration rate	29	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Hemoglobin	102	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
2021[redacted] CCYYMMDD	Sodium	150	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			Yes
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
202[redacted] CCYYMMDD	WBC	9.1	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Heart rate	Rapid	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Respiratory rate	rapid	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)
			No
Results of tests and procedures (B.3.2)			

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Alanine aminotransferase([redacted]2021):High
Aspartate aminotransferase([redacted]2021):High
Blood albumin([redacted]-2021):Low
Troponin([redacted]2021):High
Chest X-ray([redacted]2021):with slight worsening of right basilar atelectasis.
Neutrophil count([redacted]-2021):High
C-reactive protein([redacted]2021):High
Alanine aminotransferase([redacted]2021):Elevated
Blood lactic acid([redacted]2021):elevated
Blood potassium([redacted]-2021):hypokalemia
Blood sodium([redacted]2021):mild hyponatremia
Electrocardiogram([redacted]2021):she was in sinus rhythm
Computerised tomogram head([redacted]2021):Generalized atrophy noted.
Electrocardiogram([redacted]2021):Not new compared to the previous ECGs.
Blood sodium([redacted]2021):from 146 (unspecified date)
Chest X-ray([redacted]-2021):with worsening interstitial pulmonary edema, mostly on the left lower and upper zone.
Glomerular filtration rate([redacted]-2021):dropping from 46 (unspecified date)
Echocardiogram([redacted]-2021):with RVSP at 75 with moderate mitral regurgitation and moderate aortic rregurgitation.
Blood culture([redacted]2021):also reported as gram-positive cocci and Aerococcus bacteremia
White blood cell count([redacted]2021):High
Respiratory rate([redacted]2021):did not look to be in any distress
Urine analysis([redacted]2021):>= 1x10E7 CFU/L
no pyuria.
Unless there is a clinical diagnosis of UTI (e.g. dysuria, frequency, or non-localizing symptoms/signs e.g. fever, sepsis with NO other cause), this result most often represents asymptomatic bacteriuria (ASB), antibiotics are NOT indicated for ASB EX CEPT during pregnancy or prior to any urological procedure likely to cause mucosal bleeding. Changes in mental status or character of urine WITHOUT localizing urinary symptoms are NOT diagnostic of UTI.
Heart rate([redacted]2021):bpm
Oxygen saturation([redacted]2021):on 1L O2

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypothyroidism	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dementia Alzheimer's type	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
2015 CCYY	Yes	
Comments (B.1.7.1g)		
Progressive worsening since 2015, most recent MMSE thought to be 13-15, baseline GCS approximately 1		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Incontinence urinary	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	COPD	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		
Patient was never a smoker so the diagnosis is very much in doubt.		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Osteoarthritis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Dyslipidemia	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Stress incontinence	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Urge incontinence	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Nephrolithiasis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Osteoporosis	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Vitamin B12 deficiency	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	No	
Comments (B.1.7.1g)		
maintenance		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Appendectomy	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
1960 CCYY		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cataract extraction	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
2011 CCYY		
Comments (B.1.7.1g)		
right		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cataract extraction	

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Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
2012 CCYY		

Comments (B.1.7.1g)
left

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Cholecystectomy

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
1965 CCYY		

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Total abdominal hysterectomy

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
1969 CCYY		

Comments (B.1.7.1g)
with unilateral salpingo-oophorectomy

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Hip arthroplasty

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
2003 CCYY		

Comments (B.1.7.1g)
left
In the setting of a motor vehicle accident

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Urinary tract infection

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)
requiring hospitalization

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Breast biopsy

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Hysterectomy

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	GERD

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)
26.0	Bone disorder

Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

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Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Urosepsis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Bacteraemia	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Endocarditis infective	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)
CLAVULIN [AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM]

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)
v.26.0	Allergy

Drug name (B.1.8a)
CODEINE

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)
v.26.0	Drug allergy

Drug name (B.1.8a)
PENICILLIN NOS

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)
v.26.0	Allergy

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Physician	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_04571440 (3)

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04577460 (1)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210915 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101057411(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210813 CCYYMMDD	20210903 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101057411

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101057411

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) E2B_04604593, (2) , (2) E2B_04604593

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)
12 Weeks	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Baby premature
26.0	Maternal exposure during pregnancy

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EX2294	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Transplacental	Intramuscular
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Baby premature	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Baby premature	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Maternal exposure during pregnancy, first trimester	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) RABEPRAZOLE	
Active Substance names (B.4.k.2.2) rabeprazole		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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ATIA - 19(1)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MOTHER RECEIVED PFIZER COVID-19 VACCINE DURING PRENANCY/ AT 12 WEEKS GESTATION PERIOD

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Maternal exposure during pregnancy, first trimester		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Maternal exposure during pregnancy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PRETERM BIRTH AT 24 WEEKS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Baby premature		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Premature baby		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	202[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
1909 Hours	86 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Past reaction

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Drug allergy		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Drug hypersensitivity		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received from a contactable physician through COVAES. The physician reported information for both mother and fetus. This is the fetus report.

A fetus patient of unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), transplacental on [redacted]2021 11:30 (Batch/Lot Number: EX2294) as dose 1, single and transplacental o[redacted]2021 10:00 (Batch/Lot Number: FA9099) as dose 2, single, for COVID-19 immunization at the clinic. The patient's medical history was not reported. Concomitant medications included rabeprazole and ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS). The patient's mother medical history included gestational diabetes (previous pregnancy 2014), penicillin allergy, IgA nephropathy, inflammatory arthritis NOS; and previously took macrolides and had drug allergy. The patient was exposed on BNT162B2 on [redacted]2021 (at 12 weeks Gestation Period). On [redacted]2021 00:30, the patient's mother had a preterm labor resulting in emergency caesarean. Preterm birth at 24 weeks and death of newborn. The patient had died on [redacted]2021. It was unknown if an autopsy was performed.

Information on the batch/lot number has been requested.

Amendment: This follow-up is being submitted to amend previously reported information: Classification (removed At Risk classification) and Reaction details(events updated to Maternal exposure during pregnancy and Premature baby).
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

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Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Based on the information available and considering temporal association a possible contributory role of the suspect BNT162B2 cannot be completely excluded for the reported events of neonatal death owing to patient's mother having a preterm labor resulting in emergency caesarean and preterm birth at 24 weeks, and death of the newborn. The case will be reassessed further upon receipt of additional information.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Maternal exposure during pregnancy	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Baby premature	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
		40 Years	202[redacted] CCYYMMDD
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	
		Female	

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Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
v.26.0	Gestational diabetes	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		
previous pregnancy 2014		
MedDRA version (B.1.10.7.1a.1)	**Medical history (B.1.10.7.1a.2)**	
v.26.0	IgA nephropathy	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		
MedDRA version (B.1.10.7.1a.1)	**Medical history (B.1.10.7.1a.2)**	
v.26.0	Inflammatory arthritis	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		
MedDRA version (B.1.10.7.1a.1)	**Medical history (B.1.10.7.1a.2)**	
v.26.0	Penicillin allergy	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		
MedDRA version (B.1.10.7.1a.1)	**Medical history (B.1.10.7.1a.2)**	
v.26.0	Pregnancy	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
2014 CCYY		
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)		
MACROLIDES		
Drug start date (B.1.10.8c)	**Drug end date (B.1.10.8e)**	
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**	
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**	
v.26.0	Drug allergy	

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-Taiho Oncology Inc-EU-2021-02662(1)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 202[redacted] CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220411 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**	
	Company number (A.1.10.2) CA-Taiho Oncology Inc-EU-2021-02662	

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
MARKET AUTHORIZATION HOLDER	2021A862455
MARKET AUTHORIZATION HOLDER	202101746598
CANADA VIGILANCE	E2B_04997896
CANADA VIGILANCE	E2B_05028497
Taiho Oncology Inc	CA-Taiho Oncology Inc[redacted]

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(2) , (2) , (1) E2B_05028497

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - TAIHO PHARMA CANADA, INC

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Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male	159 Centimeter	63 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1951[redacted] CCYYMMDD			70 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
202[redacted] CCYYMM	

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Pneumonia

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** LONSURF	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Dose, frequency and current cycle unknown		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Oral	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Metastatic colorectal cancer
Start date of drug (B.4.k.12) 2020[redacted] CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1) 8 Months	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Drug discontinued	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pneumonia	
Source of assessment (B.4.k.18.2) Company	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Pneumonia	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)** Not Reported

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) .5 ml		
Dosage text (B.4.k.6) Solution		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunization
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Not Applicable	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Pneumonia	
Source of assessment (B.4.k.18.2) Company	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4) Not assessable
MedDRA version (B.4.k.18.1a) 26.0	Reaction assessed (B.4.k.18.1b) Pneumonia	
Source of assessment (B.4.k.18.2) Reporter	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4) Not Reported

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Pneumonia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Pneumonia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No	202[redacted] CCYYMM	202[redacted] CCYYMM	1 Months

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
8 Months		Fatal

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Summary (B.5)

Case narrative (B.5.1)

Local reference number: [redacted]

A solicited report was received from a consumer via a patient support program concerning a 70-years-old male patient treated with Lonsurf (trifluridine and tipiracil hydrochloride) tablets, (unknown dose and frequency) given orally from [redacted]2020 (unknown cycle) for metastatic colorectal cancer (mCRC). Lonsurf is approved to be administered after the morning and the evening meal, on Day 1 through Day 5, followed by a recovery period from Day 6 through Day 7. Lonsurf will again be administered on Day 8 through Day 12, followed by a recovery period from Day 13 through Day 28.

Medical history was reported as unknown.

Previously, the patient experienced energy level was 1/10 (AER No: [redacted].

Concomitant medication was reported as unknown.

Co-suspect drug included Covid vaccine (COVID-19 vaccine).

On [redacted]2021, the patient was hospitalized due to pneumonia, during which time he had received an antibiotic (unspecified) and morphine. On an unspecified date the patient received a second dose of COVID-19 vaccine, and the reporter (spouse) expressed concern if it had an impact on the patients pneumonia. The course of hospitalization was not reported. It was noted that it went very fast, not otherwise specified. At the time of reporting, the patient had passed away on an unspecified date [redacted]2021), described as one week prior. No further information was provided.

Treatment rendered included morphine and unspecified antibiotics for pneumonia.

Lab tests were reported as unknown.

Action taken with Lonsurf due to the event, pneumonia, was reported as drug discontinued on an unknown date. Action taken with Covid vaccine due to the event, pneumonia, was not applicable. The date when the last dose of Lonsurf was administered prior to the onset of the event was not reported.

The outcome of the event, pneumonia, was fatal on an unknown date in [redacted]2021. It was unknown if an autopsy was performed.

Reporter causality assessment:
The reporters assessment for the causal relationship between the event, pneumonia, and Lonsurf was not reported and for the seriousness (criteria) was serious (Death and hospitalization).
The reporters assessment for the causal relationship between the event, pneumonia, and Covid vaccine was not reported and for the seriousness (criteria) was serious (Death and hospitalization).

No additional information is expected for this report.

Initial report received on [redacted]2021.

The following information has been updated or newly reported.

This information was received from the Canadian Vigilance Database. Other manufacturer Control Number was reported.

The previously reported co-suspect medication COVID-19 vaccine was updated as Vaxzevria (COVID-19 vaccine nrvv ad (chadox1 ncov-19)).

On an unspecified date the patient passed away due to pneumonia (previously reported).

Action taken with Vaxzevria due to the event, pneumonia, was not applicable.

Reporter causality assessment:
The reporter's assessment for the causal relationship between the event, pneumonia, and Lonsurf was not reported and for the seriousness (criteria) was serious (Death and hospitalization).
The reporter's assessment for the causal relationship between the event, pneumonia, and Vaxzevria was not reported and for the seriousness (criteria) was serious (Death and hospitalization).

Follow-up 1 report was received on 11/Apr/2022.

Reporter's comments (B.5.2)

The reporter's assessment for the causal relationship between the event, pneumonia, and Lonsurf was not reported and for the seriousness (criteria) was serious (Death and hospitalization).
The reporter's assessment for the causal relationship between the event, pneumonia, and Vaxzevria was not reported and for the seriousness (criteria) was serious (Death and hospitalization).

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Pneumonia (Pneumonia):Serious (Death, Hospitalization), Related
A 70-years-old male patient with metastatic colorectal cancer (mCRC) was under treatment with Lonsurf from [redacted] 2020 (unknown cycle) when experienced pneumonia. Pneumonia is a serious event as this lead to hospitalization and death. Pneumonia is a well-known side effect for the safety profile for Lonsurf but the pneumonia with fatal outcome is considered as unlabeled. Pneumonia is assessed as related to Lonsurf.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Unknown

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pneumonia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

[redacted] energy level was 1/10

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	PRIVACY		PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
Lonsurf CONEXUS Patient Support Program	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
Lonsurf CONEXUS	Other studies

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04594271 (6)	Page#1
Canada Vigilance Adverse Reaction Report	**HC Latest Received Date:**	20220704 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-SA-2018SA310104(7)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	Serious
		Seriousness (A.1.5.2)	
Type of report Study		**Caused/prolonged hospitalization?**	Yes
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6) 20181105 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20220628 CCYYMMDD	**Disabling/Incapacitating?**	No
		Life threatening?	No
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**	
	Company number (A.1.10.2) CA-SA-SAC20210802000887	

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	**Duplicate Case identifiers (A.1.11.2)**
SA	CA-SA-SAC20220304000777
PORTAL ID	SanofiPVPortal220220303000407
SA	CA-SA-SAC00000000335152
PORTAL ID	SanofiPVPortal220220318000398
SA	CA-SA-SAC00000000335152
SA	CA-SA-SAC00000000335152
SAAVPROD	CA-SA-2018SA310104

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	**Reason for nullification (A.1.13.1)**
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

MAH - SANOFI-AVENTIS

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04594271 (6)	Page#2

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
	Adult		49 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)
			[redacted]

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2022[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Hemophagocytic lymphohistiocytosis

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ALEMTUZUMAB	
Active Substance names (B.4.k.2.2)		
alemtuzumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	7HV2644	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
12 Milligram,1 every 1 (Days) Cumulative dose to first reaction: 36 Milligram		
Dosage text (B.4.k.6)		
12 mg, QD		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous drip	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Relapsing-remitting multiple sclerosis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20181114 CCYYMMDD	20181115 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
959 Days	949 Days	3 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Drug discontinued		
Additional info (B.4.k.19)		

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Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Abdominal pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Appetite lost	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Appetite lost	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Appetite lost	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Appetite lost	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chest pain exertional	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold sores	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold sores	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold sores	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cold sores	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cough	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Diarrhea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Difficulty in walking	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Difficulty in walking	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Difficulty in walking	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Difficulty in walking	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Elevated BP	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Elevated BP	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Elevated BP	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Elevated BP	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Feeling unwell	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Feeling unwell	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Feeling unwell	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Feeling unwell	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Flu	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Flu	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Flu	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Flu	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Foot pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Foot pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Foot pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Foot pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hair loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hair loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hair loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hair loss	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemophagocytic lymphohistiocytosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemophagocytic lymphohistiocytosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemophagocytic lymphohistiocytosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemophagocytic lymphohistiocytosis	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Infusion site burning	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Infusion site burning	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Infusion site burning	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Infusion site burning	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Intermittent headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Intermittent headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Intermittent headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Intermittent headache	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Joint pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Kidney disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Kidney disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Kidney disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Kidney disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lymph node disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lymph node disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lymph node disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Lymph node disorder	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Migraine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Migraine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Migraine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Migraine	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported

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MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Nausea	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulse rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulse rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulse rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Pulse rate increased	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sickness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sickness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sickness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sickness	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sinus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sinus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sinus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sinus infection	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sore throat	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stomach pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stomach pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stomach pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stomach pain	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sweating	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sweating	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sweating	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Sweating	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Tingling of extremity	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Tingling of extremity	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Tingling of extremity	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Tingling of extremity	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vertigo	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vertigo	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vertigo	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vertigo	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Walking pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Walking pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Health Care professional	Global Introspection	Not Reported
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Walking pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Walking pneumonia	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Pharmaceutical Company	Global Introspection	Not Reportable

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) COVID-19 VACCINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 vaccination
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Suspect	Medicinal product name (B.4.k.2.1) CHADOX1 NCOV-19	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) solution intramuscul;ar		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Intramuscular	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a) 26.0	Indication (B.4.k.11b) COVID-19 immunisation
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19) Vial contains 10 doses of 0.5ml		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RANITIDINE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 150 Milligram		
Dosage text (B.4.k.6) 150 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Oral	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Premedication
Start date of drug (B.4.k.12) 20181105 CCYYMMDD	**Drug end date (B.4.k.14)** 20181115 CCYYMMDD	
Start period (B.4.k.13.1) 2 Days	**Last period (B.4.k.13.2)** 949 Days	**Duration of drug Admin (B. 4.k.15)** 11 Days
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	GRAVOL	
Active Substance names (B.4.k.2.2)		
dimenhydrinate		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
50 Milligram		
Dosage text (B.4.k.6)		
50 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20181105 CCYYMMDD	20181115 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2 Days	949 Days	11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	
Active Substance names (B.4.k.2.2)		
DIPHENHYDRAMINE HYDROCHLORIDE		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
50 Milligram		
Dosage text (B.4.k.6)		
50 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20181105 CCYYMMDD	20181115 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2 Days	949 Days	11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METHYLPREDNISOLONE	
Active Substance names (B.4.k.2.2)		
methylprednisolone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
1 Gram		
Dosage text (B.4.k.6)		
1 g, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20181105 CCYYMMDD	20181115 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2 Days	949 Days	11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACETAMINOPHEN	
Active Substance names (B.4.k.2.2)		
acetaminophen		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
12 mg		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous drip	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20181105 CCYYMMDD	20181115 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2 Days	949 Days	11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACYCLOVIR	
Active Substance names (B.4.k.2.2)		
acyclovir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
200 Milligram		
Dosage text (B.4.k.6)		
200 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20181105 CCYYMMDD	20181115 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2 Days	949 Days	11 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	GABAPENTIN	
Active Substance names (B.4.k.2.2)		
gabapentin		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
300 Milligram		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VENLAFAXINE	
Active Substance names (B.4.k.2.2) venlafaxine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 37.5 Milligram		
Dosage text (B.4.k.6) 37.5 mg, UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MIRTAZAPINE	
Active Substance names (B.4.k.2.2)		
mirtazapine		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
45 Milligram		
Dosage text (B.4.k.6)		
45 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Tablet	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NORTRIPTYLINE	
Active Substance names (B.4.k.2.2)		
nortriptyline		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
25 Milligram		
Dosage text (B.4.k.6)		
25 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) ZOLMITRIPTAN	
Active Substance names (B.4.k.2.2) zolmitriptan		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 5 Milligram		
Dosage text (B.4.k.6) 5 mg, UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) FROVATRIPTAN	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 2.5 Milligram		
Dosage text (B.4.k.6) 2.5 mg, UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NAPROXEN	
Active Substance names (B.4.k.2.2)		
naproxen		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
500 Milligram		
Dosage text (B.4.k.6)		
500 mg, UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN D	
Active Substance names (B.4.k.2.2) vitamin d		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN B 12 [VITAMIN B12 NOS]	
Active Substance names (B.4.k.2.2) vitamin b12		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VITAMIN E NOS	
Active Substance names (B.4.k.2.2) vitamin e		
Country drug obtained (B.4.k.2.3) Canada	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Unknown	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACRIVASTINE	
Active Substance names (B.4.k.2.2)		
acrivastine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACYCLOVIR SODIUM	
Active Substance names (B.4.k.2.2)		
acyclovir sodium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	FROVATRIPTAN SUCCINATE	
Active Substance names (B.4.k.2.2)		
frovatriptan succinate monohydrate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	METHYLPREDNISOLONE SODIUM SUCCINATE	
Active Substance names (B.4.k.2.2)		
methylprednisolone sodium succinate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	26.0	Premedication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1) Concomitant	Medicinal product name (B.4.k.2.1) VENLAFAXINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8) Oral	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16) Unknown	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	NORTRIPTYLINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
nortriptyline hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RANITIDINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
ranitidine hydrochloride		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Oral	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	Premedication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SICKNESS/ HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS/ PATIENT WAS DECEASED/ HLH/ HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hemophagocytic lymphohistiocytosis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Haemophagocytic lymphohistiocytosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	20210621		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
959 Days 2 Days	949 Days	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SICKNESS/ HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS/ ILLNESS

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Sickness		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Illness		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	20210621		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
959 Days	949 Days	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FEVER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fever		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pyrexia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ABDOMINAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Abdominal pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Abdominal pain		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

JOINT PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Joint pain		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Arthralgia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LYMPH NODES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Lymph node disorder		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Lymphadenopathy		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	

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		Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHEST INFECTION/WALKING PNEUMONIA/ ATYPICAL PNEUMONIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Walking pneumonia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Atypical pneumonia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Yes	201903		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
		Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NOT FEELING WELL RECURRENT/ MALAISE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Feeling unwell		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Malaise		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Yes	20181108		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
3 Days		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERMITTENT ELEVATED BP/ BLOOD PRESSURE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Elevated BP		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Blood pressure increased		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Yes	20181108 CCYYMMDD	20181114 CCYYMMDD	6 Days
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
3 Days		Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SHOCKS GOING DOWN HER LEGS ALL NIGHT, (TINGLING FEELING), THE SAME IN HER LEFT ARM/ PARAESTHESIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Tingling of extremity		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
26.0	Paraesthesia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Yes	20181107 CCYYMMDD	20181107 CCYYMMDD	1 Days
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	
2 Days		Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERMITTENT ELEVATED PULSE 121 BPM ASYMPTOMATIC/HEART RATE WAS ELEVATE TO 114/ HEART RATE INCREASED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)

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26.0	Pulse rate increased		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Heart rate increased		
Term hightlighted by the reporter? (B.2.i.3) Yes	**Start Date** (B.2.i.4) 20181105 CCYYMMDD	**End Date** (B.2.i.5) 20181107 CCYYMMDD	**Duration** (B.2.i.6) 2 Days
Reaction first time (B.2.i.7.1) 1 Days	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FLU/ INFLUENZA

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Flu		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Influenza		
Term hightlighted by the reporter? (B.2.i.3) Yes	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

INTERMITTENT HEADACHE/ HEADACHE

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Intermittent headache		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Headache		
Term hightlighted by the reporter? (B.2.i.3) Yes	**Start Date** (B.2.i.4) 20181106 CCYYMMDD	**End Date** (B.2.i.5) 20181114 CCYYMMDD	**Duration** (B.2.i.6) 8 Days
Reaction first time (B.2.i.7.1) 1 Days	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIARRHEA/ DIARRHOEA

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Diarrhea		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Diarrhoea		
Term hightlighted by the reporter? (B.2.i.3) Yes	**Start Date** (B.2.i.4) 20181108 CCYYMMDD	**End Date** (B.2.i.5) 20181114 CCYYMMDD	**Duration** (B.2.i.6) 6 Days
Reaction first time (B.2.i.7.1) 3 Days	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	**Reaction/event MedDRA term(LLT)** (B.2.i.1.b) Nausea		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	**Reaction/event MedDRA term (PT)** (B.2.i.2.b) Nausea		
Term hightlighted by the reporter? (B.2.i.3) Yes	**Start Date** (B.2.i.4) 20181108 CCYYMMDD	**End Date** (B.2.i.5) 20181114 CCYYMMDD	**Duration** (B.2.i.6) 6 Days
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	

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3 Days		Recovered/resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

MIGRANES/ MIGRAINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Migraine		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Migraine		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2019		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SWEATING/ HYPERHIDROSIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Sweating		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Hyperhidrosis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	20181218 CCYYMMDD	20181221 CCYYMMDD	3 Days
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
43 Days	33 Days	Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NO APPETITE/ DECREASED APPETITE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Appetite lost		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Decreased appetite		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	20181218 CCYYMMDD	20181221 CCYYMMDD	3 Days
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
43 Days	33 Days	Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LOST ALL OF HER HAIR

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hair loss		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Alopecia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ISSUES WITH HER KIDNEYS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Kidney disorder
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**

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26.0	Renal disorder		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Unknown	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BURNING PAIN AT IV SITE/IV NOTED TO BE PAINFUL/ INFUSION SITE PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Infusion site burning		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Infusion site pain		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4) 20181106 CCYYMMDD	End Date (B.2.i.5) 20181115 CCYYMMDD	Duration (B.2.i.6) 9 Days
Reaction first time (B.2.i.7.1) 1 Days	Reaction last time (B.2.i.7.2) 18 Minutes	Outcome (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COUGH

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Cough		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Cough		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4) 201903	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHEST FEELS LIKE STABBING KNIVES WHEN SHE COUGHS/ CHEST PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Chest pain exertional		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Chest pain		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8) Not recovered/not resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE PAIN IN HER LEFT FOOT/ PAINFUL LEFT FOOT/ PAIN IN EXTREMITY

MedDRA version for reaction/event term LLT (B.2.i.1.a) 26.0	Reaction/event MedDRA term(LLT) (B.2.i.1.b) Foot pain		
MedDRA version for reaction/event term PT (B.2.i.2.a) 26.0	Reaction/event MedDRA term (PT) (B.2.i.2.b) Pain in extremity		
Term hightlighted by the reporter? (B.2.i.3) Yes	Start Date (B.2.i.4) 20190907	End Date (B.2.i.5)	Duration (B.2.i.6)
Reaction first time (B.2.i.7.1) 306 Days	Reaction last time (B.2.i.7.2) 296 Days	Outcome (B.2.i.8) Recovered/resolved	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VERTIGO

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MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Vertigo
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Vertigo

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20190907		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
306 Days	296 Days	Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COULD NOT WALK/ GAIT DISTURBANCE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Difficulty in walking
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Gait disturbance

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20190907		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
306 Days	296 Days	Not recovered/not resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

LARGE PAINFUL COLD SORE/ ORAL HERPES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cold sores
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oral herpes

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20181217 CCYYMMDD	20181221 CCYYMMDD	4 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
42 Days	32 Days	Recovered/resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PAIN IN BELLY/ ABDOMINAL PAIN UPPER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Stomach pain
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Abdominal pain upper

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20181218 CCYYMMDD	20181221 CCYYMMDD	3 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
43 Days	33 Days	Recovered/resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

NAUSEA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Nausea
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nausea

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20181218 CCYYMMDD	20181221 CCYYMMDD	3 Days

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Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
43 Days	33 Days	Recovered/resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

COLD (RECURRENT) / A FEW BAD COLDS/SICK 2 MORE TIMES WITH BAD COLDS/ NASOPHARYNGITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Cold
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Nasopharyngitis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	201903		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Recovering/resolving

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SORE THROAT/ OROPHARYNGEAL PAIN

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sore throat
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Oropharyngeal pain

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20190429		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
175 Days	165 Days	Recovered/resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE SINUS INFECTION/ SINUSITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Sinus infection
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Sinusitis

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	201903		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Recovered/resolved

Summary (B.5)

Case narrative (B.5.1)

Initial information received on 05-Nov-2018 regarding a solicited valid non-serious case received from a consumer/ non-hcp (healthcare professional), in the scope of post-marketing sponsored study "SPON_I_ALEMTUZUMAB".

Patient ID: [redacted] Country: Canada

Study Title: PATIENT SUPPORT PROGRAM INVOLVING ALEMTUZUMAB.

This case involves a 49 years old female patient who had sickness/ hemophagocytic lymphohistiocytosis/ patient was deceased/ hlh/ haemophagocytic lymphohistiocytosis, joint pain, chest infection/walking pneumonia/ atypical pneumonia, not feeling well recurrent/ malaise, intermittent elevated bp/ blood pressure increased, shocks going down her legs all night, (tingling feeling), the same in her left arm/ paraesthesia, intermittent elevated pulse 121 bpm asymptomatic/heart rate was elevate to 114/ heart rate increased, flu/ influenza, intermittent headache/ headache, diarrhea/ diarrhoea, nausea, migranes/ migraine, sweating/ hyperhidrosis, no appetite/ decreased appetite, lost all of her hair, issues with her kidneys, burning pain at iv site/iv noted to be painful/ infusion site pain, cough, severe pain in her left foot/ painful left foot/ pain in extremity, vertigo, could not walk/ gait disturbance, large painful cold sore/ oral herpes, pain in belly/ abdominal pain upper, nausea, cold (recurrent)/ a few bad colds/sick 2 more times with bad colds/ nasopharyngitis and severe sinus infection/ sinusitis while receiving vaccine Covid-19 vaccine and while treated with alemtuzumab (Lemtrada) and covid-19 vaccine NRVV AD (chadox1 ncov-19) [Vaxzevria].

The patient's past medical history included Influenza.
The patient's past medical treatment(s), vaccination(s) and family history were not provided.
At the time of the event, the patient had ongoing Migraine, Depression, Anxiety, Urinary tract disorder (Micturition disorder), multiple sclerosis and hypertension.

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Concomitant medications included ranitidine; dimenhydrinate (Gravol); diphenhydramine hydrochloride (Benadryl [diphenhydramine hydrochloride]); Methylprednisolone; Acetaminophen; acyclovir [aciclovir] (Acyclovir [aciclovir]); Acrivastine, Acyclovir sodium; Methylprednisolone sodium succinate; Ranitidine hydrochloride for premedication; Gabapentin; Venlafaxine; Mirtazapine; Nortriptyline; Zolmitriptan; Frovatriptan; Naproxen; vitamin D [Vitamin d nos]; vitamin B12 NOS (Vitamin B 12 [vitamin B12 nos]); Vitamin E NOS; Frovatriptan succinate; Nortriptyline hydrochloride; and Venlafaxine hydrochloride.

On 05-Nov-2018, the patient started taking alemtuzumab, concentration for solution for infusion, at dose of 12 mg daily dose intravenous drip (lot - 7HV2644) for Relapsing-remitting multiple sclerosis. On the same day patient had intermittent elevated pulse 121 bpm asymptomatic (blood pressure increased; heart rate increased).
On 06-Nov-2018, patient had intermittent headache (headache) and burning pain at IV site (infusion site pain; latency: 1 day) and on the same day IV was removed and new one was inserted at right hand.
On 07-Nov-2018, patient completed his treatment with alemtuzumab. On same day, patient experienced shocks going down her legs all night, (tingling feeling), the same in her left arm (paraesthesia; latency: 2 days) and her heart rate was elevated to 114 lasting about 20 seconds. All this happened when lying down and resolved when she got up. On 07-Nov-2018, patient recovered from Intermittent Elevated pulse 121 bpm asymptomatic, shocks going down her legs all night, (tingling feeling), the same in her left arm. Patient reported getting shocks in her legs periodically but not usually both legs at one time.
On 08-Nov-2018, 3 days after receiving Lemtrada in the morning patient had elevated BP 161/116, 142/112, 148/110 also patient stated not feeling well with diarrhea (6 times) since 2 am, so loperamide hydrochloride (Imodium) (diarrhoea) was taken also patient had nausea (nausea) since 4 am and dimenhydrinate (Gravol) was taken. Patient also had headache throughout the night, so paracetamol (Tylenol) was taken. Patient contacted referring physician, and he requested to hold the infusion and send patient to ER for further assessment.
On 14-Nov-2018 the infusion was re-started, and it was done for 2 days. The same day, the patient recovered from the events or intermittent headache, not feeling well (malaise), intermittent elevated BP 161/116, diarrhea and nausea.
On 15-Nov-2018 the infusion was noted to be painful and so intravenous drip was removed and replaced.
On 17-Dec-2018, after 1 month 12 days of treatment with alemtuzumab, patient experienced large painful cold sore (oral herpes) in the morning. No other information was provided.
On 18-Dec-2018, patient experienced, pain in belly (abdominal pain upper), nausea, sweating (hyperhydrosis), no appetite (decreased appetite). It was reported that the patient suspected it might be the flu (influenza).
On 21-Dec-2018, the patient recovered from pain in belly, large painful cold sore, nausea, sweating and no appetite which lasted for about 3 days. She took Tylenol, anti-nausea pills and went back on her antivirals.
On an unknown date in Mar-2019 since the last three weeks Patient was really sick with the worst cold of her life (nasopharyngitis) and her chest feels like stabbing knives (chest pain) when coughed (cough) and had a sinus infection (sinusitis) and chest infection and was still sick. Patient would be seeing doctor again today. Patient had been sick for 3 weeks now. Patient saw doctor and was diagnosed with a severe sinus infection and walking pneumonia (atypical pneumonia; medically significant). Patient was put on Clavulanic. As follow up, patient reported her infections had resolved on an unknown date in 2019.
Patient had a sore throat (oropharyngeal pain) on 29-Apr-2019 and now had a full-fledged cold. If her symptoms worsen, she will go to the doctors. The patient reported the antibiotics worked very well and did clear it all up. She had been sick two more times with bad colds since Apr-2019, but she was recovering. On an unknown date 2 weeks ago, the patient had migraines (migraine).
On 07-Sep-2019 (10 months 2 days) the patient could not walk due to severe pain in her left foot (pain in extremity) and vertigo. The foot was better now, but she still had vertigo. No further information provided.
Patient reported she had suffered chronic migraines since the age of 12, but they had been terrible this last month. She was taking frovatriptan and zolmitriptan (Zomig) as treatment.
On an unknown date, the patient received a dose of suspect COVID-19 vaccine not produced by Sanofi Pasteur lot number not reported via unknown route and VAXZEVRIA (COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)) at an unknown dose intramuscular (with an unknown batch number) for COVID-19 immunisation
On 21-Jun-2021 after a latency of 2 years 7 months 16 days the patient was in intensive care unit for sickness (illness) and did not known when she would be discharged. She was pretty sick right now and the doctors were unsure if it was because of alemtuzumab or COVID-19 vaccine.
She returned home on 29-Jun-2021 after being in hospital for 40 days. She was diagnosed with hemophagocytic lymphohistiocytosis (haemophagocytic lymphohistiocytosis; medically significant) and is being treated with chemotherapy. She is off all her multiple sclerosis medication until levels normal out and she has finished her chemotherapy
Follow up to previously reported hospitalization in the intensive care unit with onset date: 21 June 2021 Patient reported she was not well and is getting her blood work done twice a week plus chemotherapy. She is being followed by Rheumatology. They feel her Lemtrada caused the hemophagocytic lymphohistiocytosis (HLH). No further information given. Corrective treatment: chemotherapy, blood work twice a week.
As follow up patient for hospitalization on 21 June 2021 reported she was admitted back into the intensive care unit on September 17, 2021 and was still there. and as Corrective treatment: chemotherapy, blood work twice a week. The patient reported she was back in the intensive care unit for a week, but was back home now. On an unknown date after unknown latency patient reported having issues with kidney (renal disorder) and lost all her hair (alopecia). Program received blood work completion report from neurologist office which stated patient was deceased (death, fatal, medically significant).
Upon follow-up, it was reported that, on an unknown date and latency, the patient began experiencing fever (Pyrexia), joint pain (Arthralgia), abdominal pain, lymph nodes (Lymphadenopathy) and headache and died on [redacted] 2022 due to HLH. The patient had serum ferritin at a value of >500 Âµg/L and other diagnostic tests used to confirm the diagnosis of HLH were: Alkaline Phosphatase, Bilirubin, Prothrombin time/ international normalized ratio (PT/INR), hemoglobin, leukocytes, creatinine, urea, lipid panel with fasting triglycerides, Cranial CT (Computer tomography)
Immunosuppressive therapy with cyclosporine/ etoposide/ Prednisone Outcome for HLH: Death [redacted] 2022.

Action taken: drug withdrawn for intermittent elevated bp, not feeling well, intermittent headache, diarrhea, nausea, no action taken for burning pain at iv site, elevated pulse, shocks going down her legs, not applicable for rest of the events

Corrective treatment: Immunosuppressive therapy with cyclosporine/ etoposide/ Prednisone for hemophagocytic lymphohistiocytosis , Clavulanic for chest infection/walking pneumonia, severe sinus infection, Tylenol for intermittent headache; gravol for nausea; immodium for diarrhea, Tylenol, anti-nausea pills, anti-viral pills for pain in belly, Large painful cold sore, nausea, sweating and no appetite, antibiotic for cold (recurrent)/ a few bad colds/sick 2 more times with bad colds, not reported issues with her kidneys and has lost all of her hair; none for rest of the events.

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Outcome: Fatal for Haemophagocytic lymphohistiocytosis, Not Recovered / Not Resolved for the event not feeling well recurrent, Unknown for the event flu, alopecia, renal disorder; was Recovering / Resolving for the event cold (recurrent)/ a few bad colds/sick 2 more times with bad colds, Not Recovered / Not Resolved for the event migranes, was Not Recovered / Not Resolved for the event could not walk, Not Recovered / Not Resolved for the event vertig0; Recovered / Resolved for rest of the events.

Reporter causality: related for Haemophagocytic lymphohistiocytosis and malaise; not reported for rest all the events.

Company causality: not reportable for death, sickness/ hemophagocytic lymphohistiocytosis, alopecia, renal disorder, Sweating, No Appetite, burning pain at IV site/IV noted to be painful, Cough, chest feels like stabbing knives when she coughs, Chest infection/walking pneumonia, large painful cold sore, pain in belly, Nausea, cold (recurrent)/ a few bad colds/sick 2 more times with bad colds, severe Sinus infection, migraine, could not walk, severe pain in her left foot and vertigo, and reportable for rest all the events.

Additional information received on 14-Nov-2018 from patient. regimen was updated. Stop date of concomitant drugs added. Event term of elevated BP updated to intermittent elevated BP. Event term of burning pain at IV site updated to burning pain at IV site. Clinical course updated and text amended accordingly.

Additional information was received on 17-Dec-2018 from a patient. Additional event of large painful cold sore was added. Clinical course updated and text amended accordingly.

Additional information was received on 18-Dec-2018 from patient. Additional events of pain in belly, nausea, sweating, no appetite and flu were added in detail. Clinical course was updated and text was amended accordingly.

Additional information was received on 14-Jan-2019 from patient. Outcome updated for pain in belly, large painful cold sore, nausea, sweating and no appetite and corrective treatment was added for same. Clinical course was updated and text was amended accordingly.

Additional information was received on 26-Mar-2019 from non-healthcare professional. new events of cold and cough was added with details. clinical course was updated and text amended accordingly.

Additional information was received on 05-Apr-2019 from patient. event chest infection/walking pneumonia, severe sinus infection were added with details. Start date for event cold and cough were added with details. Upon internal review formulation of suspect dug was updated to unknown. Clinical course was updated, and text amended accordingly.

Additional information was received on 02-May-2019 from patient. outcome of the events cough, Severe Sinus infection, Chest infection/walking pneumonia were updated to recovered. Verbatim was updated for event of cold. A new event of sore throat was added with details. Clinical course was updated and text amended accordingly.

Additional information received on 10-Jun-2019 from patient. Outcome of sore throat was updated from unknown to recovered; cold (recurrent) was updated from unknown to recovering. Verbatim of cold (recurrent) was updated to cold (recurrent)/ a few bad colds/sick 2 more times with bad colds. Clinical course was updated. Text amended accordingly. Upon internal review sore throat was updated as symptom of cold (recurrent)/ a few bad colds/sick 2 more times with bad colds.

Additional information received on 12-Sep-2019 from patient. Additional event of migraine could not walk, severe pain in her left foot and vertigo added. Clinical course was updated, and text amended accordingly.

Additional information received on 21-Oct-2019 from patient: Corrective treatment drugs added for the event of migraines, medical history added. Action taken updated. Clinical course updated and text was amended accordingly.

Additional information was received on 06-Jul-2021 from the patient. This case initially considered as non-serious was upgraded to serious for as the event of sickness with seriousness criteria: hospitalization was added. Concomitant medication was added. Event of sickness was added. Cosuspect was added. Clinical course updated and text was amended accordingly.

Additional information was received on 30-Jul-2021 from the patient. Event verbatim of sickness/ hemophagocytic lymphohistiocytosis was updated. This case initially considered as non-serious was upgraded to serious for as the event of sickness/ hemophagocytic lymphohistiocytosis was added. Clinical course updated and text was amended accordingly.

Additional information was received on 18-Aug-2021 from the patient via call center. outcome for event sickness/ hemophagocytic lymphohistiocytosis was updated. Verbatim and outcome for event not feeling well was updated. Causality updated. Clinical course was updated and text was amended accordingly.

Additional information was received on 20-Sep-2021 from patient. Clinical course was updated and text was amended accordingly.

Additional information was received on [redacted] 2021 from patient. Outcome of event of Haemophagocytic lymphohistiocytosis was updated. Text amended.

Additional information received on [redacted] 2021 from the patient. Event of alopecia, renal disorder were added. Clinical course updated and text amended accordingly.

Additional information received on [redacted] 2022 from physician. New event of death was added. Text amended accordingly.

Additional information was received on [redacted] 2022 from the physician. Event verbatim was updated for Haemophagocytic lymphohistiocytosis and additional symptoms of fever, joint pain, abdominal pain, lymph nodes, headache were added. Date of death was added. Text amended accordingly.

Additional information was received on 28-Jun-2022 from physician. The case 2022SA129724(to be deleted) was identified to be duplicate of 2018SA310104(to be retained). Hence, all the information from the case 2022SA129724 has been merged in the case 2018SA310104. Upon internal review, event verbatim and concomitants was updated. Text amended accordingly.

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Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
	Ferritin		
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)
			Yes

Results of tests and procedures (B.3.2)

Test Name: Serum ferritin,Date: , Notes: >500;

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Migraine	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Flu	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Depression	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Anxiety	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Micturition disorder	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Multiple sclerosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hypertension	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemophagocytic lymphohistiocytosis	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
PATIENT SUPPORT PROGRAM INVOLVING ALEMTUZUMAB	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
SPON_I_ALEMTUZUMAB	Other studies

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No
PATIENT SUPPORT PROGRAM INVOLVING ALEMTUZUMAB	

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)
SPON_I_ALEMTUZUMAB	Other studies

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

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Receiver (A.3.2)

Type (A.3.2.1)		**Organization** (A.3.2.2a)
Department (A.3.2.2b)		**Title** (A.3.2.2c)
Given name (A.3.2.2d)	**Middle name** (A.3.2.2e)	**Family name** (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		**State** (A.3.2.3c)
Postcode (A.3.2.3d)		**Country** (A.3.2.3e)
Tel no. (A.3.2.3f)		**Fax no.** (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04606097 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210830 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-MODERNATX, INC.-MOD-2021-293182(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210820 CCYYMMDD	20210820 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
Yes		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

E2b Differences Report

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2) CA-MODERNATX, INC.-MOD-2021-293182

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
irms QMODERNAP	CA-irms-MDCA21-02677 CA-MODERNATX, INC.-MOD-2021-293182

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - MODERNA BIOPHARMA CANADA CORPORATION

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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Canada Vigilance AER#:	E2B_04606097 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	SPIKEVAX 5 ML VIAL	
Active Substance names (B.4.k.2.2)		
elasomeran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02510014 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
1 Dosage forms		
Dosage text (B.4.k.6)		
1 dosage form		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 vaccination
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MAH	Global Introspection	Possible
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
Non-Health care professional	Global Introspection	Not Provided

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIED AFTER GETTING THE VACCINE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Died after getting the vaccine) in a patient of an unknown age and gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.

No Medical History information was reported.

On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

No concomitant medications were reported.

Treatment information was not provided.

The reporter stated that there were limited information on adverse event.

Company comment:

Extremely limited provided in the case. Critical details such as therapy date, onset, patient's medical history, clinical details pertaining to fatal outcome are all lacking. Hence, causal association cannot be ascertained. No further information is expected.

Reporter did not allow further contact

Most recent FOLLOW-UP information incorporated above includes:
On 20-Aug-2021: Upon internal review on 30-AUG-2021 action taken was corrected from unknown to Not applicable

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Extremely limited provided in the case. Critical details such as therapy date, onset, patient's medical history, clinical details pertaining to fatal outcome are all lacking. Hence, causal association cannot be ascertained. No further information is expected.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

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Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

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Canada Vigilance AER#:	E2B_04606097 (1)	Page#6

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

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Canada Vigilance AER#:	E2B_04618728 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210923 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-202101102429(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	**MAH/Sponsor Latest Received Date (A.1.7)**	Disabling/Incapacitating?	No
20210824 CCYYMMDD	20210916 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-PFIZER INC-202101102429

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
PFIZERINC	CA-PFIZER INC-202101102429

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			18 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04618728 (1)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Yes

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

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ATIA - 19(1)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML	
Active Substance names (B.4.k.2.2)		
tozinameran		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada	EY0578	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02509210 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
DOSE 1, SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	26.0	COVID-19 immunisation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
202[redacted] CCYYMMDD	2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
17 Days	17 Days	1 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
ExpDT=31-OCT-2021		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Unknown cause of death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04618728 (1)	Page#4

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CANNOT MAKE ANY CONCLUSION FOR THE REASON OF DEATH/NOT SURE IF VACCINE RELATES TO THE DEATH OR NOT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Unknown cause of death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	202[redacted]		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
17 Days	17 Days	Fatal

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report received via COVAES from a non-contactable physician. An 18-year-old female patient (not pregnant at time of vaccination) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on [redacted]2021 (Batch/Lot Number: EY0578, expiration date: 31Oct2021) (at the age of 18-years-old) as dose 1, single for covid-19 immunisation. The most recent COVID-19 vaccine was administered at Public Health Clinic/Veterans Administration facility. Medical history was None. There were no known allergies. There was no relevant past drug history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no concomitant medications received within 2 weeks of vaccination. The healthy patient was noticed diseased in her bed by parents on [redacted]2021. Autopsy was taken but cannot make any conclusion for the reason of death. She had Pfizer vaccine on [redacted]2021, not sure if vaccine related to the death or not. There was no treatment received. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient died on [redacted]2021. Autopsy was done. Autopsy-determined cause of patient death was No. There were no autopsy remarks. Subsequently, information from product quality complaint team regarding physician's complaint about BNT162B2 (COMPOUND BNT162 COVID-19 VACCINE SUSPENSION FOR INTRAMUSCULAR 2ML MULTIPLE DOSE VIAL X 1, lot: EY0578, expiration date: 31Oct2021) included: Brief complaint description: PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE - EY0578 - Adverse Event Safety Request For Investigation; Reasonably Suggest Device Malfunction? blank; Severity of Harm: N/A; Complaint Class: External Cause Investigation; Complaint Sub-Class: Adverse Event Safety Request For Investigation. Root Cause: Process Related: No; Final Confirmation Status: Not Confirmed; Vendor Related: No; Lot-Specific Trend Identified: No; Lot Trend Assmt. & Rationale: The complaint history for the reported PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE lot EY0578 was reviewed. As of 10Sep2021, this is the only complaint that has been received for this lot and classification. No lot specific trend was identified that would require additional investigation; Lot Trend Actions Taken: There were no lot trend actions taken as a result of this investigation; Other Trend Identified?: No; Other Trend Assmt. & Rationale: N/A; Site Sample Status: Not Received; Summary of Investigation from Kalamazoo (EP) division was: The initial scope of the investigation was limited to the reported finished goods lot EY0578, fill lot EY0539, and the bulk formulated drug product lot EP8644. Based on the results of the investigation, the scope was not expanded. Manufacturing and packaging batch records were examined. Pfizer Kalamazoo QO did not receive photographs or a return complaint sample for examination. The complaint was not confirmed. No related quality issues were identified during the investigation. There were no planned or unplanned deviations recorded during the manufacture of the lot that may have caused a complaint of this nature. A review of the manufacturing and packaging records confirmed all processing steps met established requirements, all noted defects were within limits and discarded, elapsed time tracking was within limits, and the freezer storage was acceptable. There were no product quality defects observed during the examination of retained reference samples. There is no impact to the quality of the lot. It is unknown how the product was handled, stored, or administered after it left the Kalamazoo site; Investigational report conclusion from Kalamazoo (EP) division was: The complaint for an adverse event requested by Safety with the use of the PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE lot EY0578 was investigated. The investigation included reviewing manufacturing and packaging batch records, retained reference samples, deviation investigations and an analysis of the complaint history for the reported lot. The final scope was determined to be the reported finished goods lot EY0578, fill lot EY0539 and the bulk formulated drug product lot EP8644. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality. The complaint was not confirmed.

No follow-up attempts are possible. No further information is expected.

Follow-up (16Sep2021): New information received from product quality complaint team included: expiration date, investigational results.

No follow-up attempts are needed. No further information expected.
BNT162B2 approved under Interim Order in Canada.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

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Based on the information in the case report and a plausible temporal relationship, a possible causal relationship between the event death and suspect drug BNT162B2 cannot be excluded.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Unknown cause of death	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

List of non-encoded Patient Relevant History:
Patient Other Relevant History 1: none

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Canada Vigilance AER#:	E2B_04618728 (1)	Page#6

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Physician

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

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Canada Vigilance AER#:	E2B_04149686 (7)	Page#1
Canada Vigilance Adverse Reaction Report	**HC Latest Received Date:**	20211203 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-PFIZER INC-2021498435(8)

Primary source country (A.1.1) Canada	**Occur country (A.1.2)**	**Serious? (A.1.5.1)**	**Serious**
		Seriousness (A.1.5.2)	
Type of report Spontaneous		**Caused/prolonged hospitalization?**	**Yes**
		Results in death?	**Yes**
MAH/Sponsor Initial Received Date (A.1.6) 20210504 CCYYMMDD	**MAH/Sponsor Latest Received Date (A.1.7)** 20211122 CCYYMMDD	**Disabling/Incapacitating?**	**No**
		Life threatening?	**No**
Additional documents? (A.1.8.1) No		**Congenital anomaly/birth defect?**	**No**
		Other medically important condition?	**Yes**

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9) Yes	**Regulatory authority's number (A.1.10.1)**	
	Company number (A.1.10.2) CA-PFIZER INC-2021498435	

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	**Duplicate Case identifiers (A.1.11.2)**
Health canada Atnahs Limited Atnahs Limited Health canada AstraZeneca Bristol-Myers Squibb company Health canada PFIZERINC	E2B_04149686 CA-Atnahs Limited-ATNAHS20211124694 ATNAHS20211124694 CA-HEALTHCANVIG-E2B_04149686 CA-AstraZeneca-2021A848073 CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-050842 CA-HEALTHCANVIG-000946849 CA-PFIZER INC-2021498435

Duplicate (D) / Link (L) Report number(s) (A.1.12)

(1) 000946849, (1) E2B_04216152

Report nullification? (A.1.13) No	**Reason for nullification (A.1.13.1)**

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - PFIZER

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04149686 (7)	Page#2

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			91 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
2021[redacted] CCYYMMDD	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
26.0	Cerebral bleeding
26.0	Chills
26.0	Craniocerebral injury
26.0	Fall
26.0	Hemorrhagic stroke
26.0	Pyrexia
26.0	Stroke
26.0	Subarachnoid haemorrhage
26.0	Subdural haemorrhage
26.0	Vomiting

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)
Suspect	COMIRNATY PURPLE CAP VIAL (12+ YEARS) AFTER DILUTION CONTAINS 6 DOSES OF 0.3 ML

Active Substance names (B.4.k.2.2)

tozinameran

Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)
Canada	

Holder and authorization/application no. of drug (B.4.k.4)

Authorization/Application no.: 02509210
Country of authorization/application: Canada

Structured dosage info (B.4.k.5)

.3 ml 1 (Total)

Dosage text (B.4.k.6)

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ATIA - 19(1)

Canada Vigilance AER#:	E2B_04149686 (7)	Page#3
DOSE 2, 0.3 ML SINGLE		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** COVID-19 immunisation
Start date of drug (B.4.k.12) 2021[redacted] CCYYMMDD	**Drug end date (B.4.k.14)** 2021[redacted] CCYYMMDD	
Start period (B.4.k.13.1) 35 Hours	**Last period (B.4.k.13.2)** 35 Hours	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral bleeding	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral bleeding	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chills	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chills	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Craniocerebral injury	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Craniocerebral injury	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Fall	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Vomiting	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Vomiting	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A

Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **ELIQUIS FILM COATED**	
Active Substance names (B.4.k.2.2) apixaban		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 5 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6) 5 milligram, bid		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Oral	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Cerebrovascular accident prophylaxis
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral bleeding	

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Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Cerebral bleeding	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chills	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Chills	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Craniocerebral injury	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Craniocerebral injury	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Unrelated
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Drug characterization (B.4.k.1)	**Medicinal product name (B.4.k.2.1)**
Suspect	**ATENOLOL**
Active Substance names (B.4.k.2.2)	
atenolol	
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**

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Holder and authorization/application no. of drug (B.4.k.4) Authorization/Application no.: 02255634 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5) 50 Milligram,2 every 1 (Days)		
Dosage text (B.4.k.6) 50 mg, 2x/day		
Pharmaceutical form (B.4.k.7) Tablet	**Route of administration (B.4.k.8)** Oral	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 26.0	**Indication (B.4.k.11b)** Atrial fibrillation
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral bleeding	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Cerebral bleeding	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chills	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Chills	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a) 26.0	**Reaction assessed (B.4.k.18.1b)** Craniocerebral injury	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

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26.0	Craniocerebral injury	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fall	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Fever	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Hemorrhagic stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Stroke	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
26.0	Subarachnoid haemorrhage	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	N/A

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MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Subdural haemorrhage	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PHARMACEUTICAL COMPANY	Global Introspection	N/A
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
26.0	Vomiting	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)
PRIMARY SOURCE REPORTER	Global Introspection	N/A

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

STROKE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Stroke		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Cerebrovascular accident		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	2021[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
35 Hours	35 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRAIN BLEED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Cerebral bleeding		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Cerebral haemorrhage		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
35 Hours	35 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HEMORRHAGIC CEREBROVASCULAR ACCIDENT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Hemorrhagic stroke		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
26.0	Haemorrhagic stroke		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	2021[redacted]		
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	

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35 Hours	35 Hours	Fatal

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FEVER

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Fever		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Pyrexia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
14 Hours	14 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CHILLS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Chills		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Chills		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
14 Hours	14 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

VOMITING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Vomiting		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Vomiting		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	2021		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
14 Hours	14 Hours	Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CRANIOCEREBRAL INJURY

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
26.0	Craniocerebral injury		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
26.0	Craniocerebral injury		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes			
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
		Fatal	

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUBARACHNOID HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Subarachnoid haemorrhage
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Subarachnoid haemorrhage

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Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Yes				
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SUBDURAL HAEMORRHAGE

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Subdural haemorrhage
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Subdural haemorrhage

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Yes				
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Fatal		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

FALL

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
26.0	Fall
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
26.0	Fall

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)	
Yes				
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)		
		Fatal		

Summary (B.5)

Case narrative (B.5.1)

This is a spontaneous report via COVAES from a contactable other health care professional (patient's niece), physician and consumer. A 91-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration, administered in the right arm on [redacted]2021 13:00 (at the age of 91 years old) as dose 2, single for COVID-19 immunization; apixaban (ELIQUIS), oral from an unspecified date (batch/lot number was not reported) to an unspecified date, at 5 mg, 2x/day for cerebrovascular accident prophylaxis; and atenolol, oral from an unspecified date (batch/lot number was not reported) to an unspecified date, at 50 mg, daily for atrial fibrillation. Medical history included left middle cerebral artery (MCA) stroke on 26Apr2017 (also reported in May2017); ongoing atrial fibrillation (on Eliquis 5mg oral 2x/day and atenolol 50mg oral daily); (recurrent) transient ischemic attack (TIA) in 2011; coronary artery disease (CAD) in 2013 (crestor 5mg oral daily). The patient was not pregnant at the time of vaccination. The patient's concomitant medications were not reported. The patient previously took the first dose of COVID-19 Vaccine (MANUFACTURER UNKNOWN) for COVID-19 immunization. The patient experienced stroke, brain bleed, hemorrhagic cerebrovascular accident on [redacted]2021, fever, chills and vomiting on [redacted]2021 03:00. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On [redacted]2021 at 03:00, the patient became extremely sick, she had fever, chills and vomiting. Later that evening (as reported; pending clarification), she passed away from a stroke and brain bleed. The adverse events resulted in emergency room, department or urgent care. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. On [redacted]021, reported relevant tests was unknown, patient was admitted and treated in the hospital. Date of death was on [redacted]2021. Patient was admitted to hospital on [redacted]2021 and died of hemorrhagic cerebrovascular accident (CVA). The action taken in response to the events for apixaban and atenolol was not applicable. The outcome of the events fever, chills and vomiting was unknown while the outcome of all other events was fatal. The patient died on [redacted]2021. It was not reported if an autopsy was performed.

Follow-up (20May2021): New information was received from a contactable physician in response to a HCP follow up questionnaire includes reporter, medical history, co-suspect products, death date, events seriousness criteria and hospital start date.

No follow up attempts are possible; Information about lot/batch number cannot be obtained.

Follow-up (20May2021): New information received from LP-BRISTOL-MYERS SQUIBB COMPANY includes suspect drug details (updated ELIQUIS as company drug) and additional reference number CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-050842.

Follow-up (05Jul2021): This follow-up is being submitted to notify that the lot/batch number for one dose is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Follow-up (05Jul2021): This is a follow-up spontaneous report, from a contactable physician via CanadaHealth Authority, Health Canada (regulatory authority number: CA-HEALTHCANVIG-000946849), based on the information received by Pfizer from Bristol-Myers Squibb (manufacturer control number: CA-BRISTOL-MYERS SQUIBB COMPANY-

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BMS-2021-050842), license party for apixaban (ELIQUIS).

This case was initially received via Pfizer Inc (Reference number: 2021498435) on 20-May-2021. The most recent information was received on 05-Jul-2021 and was forwarded to BMS on 05-Jul-2021. This spontaneous case was reported by a physician and describes the occurrence of fatal haemorrhagic stroke (Stroke; Cerebral bleeding/ Hemorrhagic CVA), fatal craniocerebral injury, fatal fall, fatal subarachnoid haemorrhage and fatal subdural haemorrhage in 91-year-old female patient who received apixaban (ELIQUIS) for cerebrovascular accident prophylaxis. Co-suspect products included BNT162B2 for COVID-19 immunization. The patient's past medical history included CVA on 26-Apr-2017, TIA (Recurrent TIA in 2011) in 2011 and coronary artery disease in 2013. Concurrent medical conditions included AFib. On an unknown date, the patient started ELIQUIS (oral), 5 milligram twice a day and BNT162B2 (unknown route). On an unknown date, the patient experienced haemorrhagic stroke (seriousness criteria death, hospitalization and medically significant), craniocerebral injury (seriousness criteria death and medically significant), fall (seriousness criterion death), subarachnoid haemorrhage (seriousness criteria death and medically significant) and subdural haemorrhage (seriousness criteria death and medically significant). The patient was hospitalized on [redacted]-2021 due to haemorrhagic stroke. The action taken with ELIQUIS (oral) was not applicable. The patient died on [redacted]2021. The reported cause of death was hemorrhagic CVA, craniocerebral injury, fall, subarachnoid haemorrhage and subdural haemorrhage. It is unknown if an autopsy was performed. Apixaban was used for Afib. Patient was admitted and treated in the hospital. Patient was admitted to hospital on [redacted]2021 and died of hemorrhagic CVA. For ELIQUIS (oral), the reporter did not provide any causality assessments. Case received from Canada health authority: CA-HEALTHCANVIG-000946849. Correction to this file was done on 28-May-2021, based on the information previously received on 20-MAY-2021 following change was made: BNT162B2 was coded as co-suspect product in the product tab (previously coded as Covid-19 Vaccine). Most recent follow-up information received from consumer via Canada HA on 05-Jul-2021 incorporated above includes: Added new events. Further company followup with the physician is not possible.

Follow-up (01Sep2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Follow-up (07Sep2021): This is a follow-up spontaneous report, from a contactable physician via Canada Health Authority, Health Canada (regulatory authority number: CA-HEALTHCANVIG-000946849), based on the information received by Pfizer from Bristol-Myers Squibb (manufacturer control number: CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-050842), license party for apixaban (ELIQUIS).

This case was initially received via Pfizer Inc (Reference number: 2021498435) on 20-May-2021. The most recent information was received on 07-Sep-2021 and was forwarded to BMS on 07-Sep-2021. This spontaneous case was reported by a physician and describes the occurrence of fatal HAEMORRHAGIC STROKE (Stroke; Cerebral bleeding/ Hemorrhagic CVA), fatal CRANIOCEREBRAL INJURY, fatal FALL, fatal SUBARACHNOID HAEMORRHAGE, fatal SUBDURAL HAEMORRHAGE, fatal CHILLS, fatal PYREXIA and fatal VOMITING in 91-year-old female patient who received apixaban (Eliquis) film-coated tablet for Cerebrovascular accident prophylaxis. CO-SUSPECT PRODUCTS included Bnt162b2 for COVID-19 immunization and Atenolol for Atrial fibrillation. The patient's past medical history included CVA on 26-Apr-2017, TIA (Recurrent TIA in 2011) in 2011 and Coronary artery disease in 2013. Concurrent medical conditions included AFib. On an unknown date, the patient started Eliquis (Oral), 5 milligram twice a day, Bnt162b2 (unknown route) contains 6 doses of 0.3 ml after dilution and Atenolol (Oral), 50 milligram once a day. On an unknown date, the patient experienced HAEMORRHAGIC STROKE (seriousness criteria death, hospitalization and medically significant), CRANIOCEREBRAL INJURY (seriousness criteria death and medically significant), FALL (seriousness criterion death), SUBARACHNOID HAEMORRHAGE (seriousness criteria death and medically significant), SUBDURAL HAEMORRHAGE (seriousness criteria death and medically significant), CHILLS (seriousness criteria death and hospitalization), PYREXIA (seriousness criteria death and hospitalization) and VOMITING (seriousness criteria death and hospitalization). The patient was hospitalized on [redacted]021 due to Haemorrhagic stroke. The action taken with Eliquis(Oral) was unknown. The patient died on [redacted]2021. The reported cause of death was hemorrhagic cva, Craniocerebral injury, Fall, Subarachnoid haemorrhage, Subdural haemorrhage, Chills, Pyrexia and Vomiting. It is unknown if an autopsy was performed. Apixaban was used for Afib. Patient was admitted and treated in the hospital. Patient was admitted to hospital on [redacted]2021 and died of hemorrhagic CVA. Action taken with suspect therapies in response to events were not reported. For Eliquis(Oral), the reporter did not provide any causality assessments. Case received from Canada health authority: CA-HEALTHCANVIG-000946849.

Followup (25Nov2021): This is a spontaneous follow-up report received from a contactable reporter healthcare professional from Regulatory Authority, via License Party (Bristol-Myers Squibb).Regulatory number: CA-HEALTHCANVIG-000946849 (Health canada), CA-HEALTHCANVIG-E2B_04149686 (Health canada). Other Case identifiers: CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-050842 (Bristol-Myers Squibb Company).

This case was initially received via Pfizer Inc (Reference number: 2021498435) on 20-May-2021. The most recent information was received on 25-Nov-2021 and was forwarded to BMS on 25-Nov-2021. This spontaneous case was reported by a physician and describes the occurrence of fatal HAEMORRHAGIC STROKE (Stroke; Cerebral bleeding/ Hemorrhagic CVA), fatal CRANIOCEREBRAL INJURY, fatal FALL, fatal SUBARACHNOID HAEMORRHAGE, fatal SUBDURAL HAEMORRHAGE, fatal CHILLS, fatal PYREXIA and fatal VOMITING in 91-year-old female patient who received apixaban (Eliquis) film-coated tablet for Cerebrovascular accident prophylaxis. CO-SUSPECT PRODUCTS included Bnt162b2 for COVID-19 immunization and Atenolol tablet for Atrial fibrillation. The patient's past medical history included CVA on 26-Apr-2017, TIA (Recurrent TIA in 2011) in 2011 and Coronary artery disease in 2013. Concurrent medical conditions included AFib. On an unknown date, the patient started Eliquis (Oral), 5 milligram twice a day, Bnt162b2 (unknown route) at single dose and Atenolol (Oral), 50 milligram once a day. On an unknown date, the patient experienced HAEMORRHAGIC STROKE (seriousness criteria death, hospitalization and medically significant), CRANIOCEREBRAL INJURY (seriousness criteria death and medically significant), FALL (seriousness criteria death and medically significant), SUBARACHNOID HAEMORRHAGE (seriousness criteria death and medically significant), SUBDURAL HAEMORRHAGE (seriousness criteria death and medically significant), CHILLS (seriousness criteria death, hospitalization and medically significant), PYREXIA (seriousness criteria death, hospitalization and medically significant) and VOMITING (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized on [redacted]2021 due to Haemorrhagic stroke. The action taken with Eliquis(Oral) was unknown. The patient died on [redacted]2021. The reported cause of death was hemorrhagic cva, Craniocerebral injury, Fall, Subarachnoid haemorrhage, Subdural haemorrhage, Chills, Pyrexia and Vomiting. It is unknown if an autopsy was performed. Apixaban was used for Afib. The patient received co-suspect drug BNT162B2 vial contains 6 doses of 0.3 ml after dilution in intramuscular suspension at a frequency of total with therapy duration of 1 day. The patient received atenolol in tablet dosage form. Patient was admitted and treated in the hospital. Patient was admitted to hospital on [redacted]2021 and died of hemorrhagic CVA. Action taken with suspect therapies in response to events were not reported. For Eliquis(Oral), the reporter did not provide any causality assessments. Case received from

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Canada health authority: CA-HEALTHCANVIG-000946849 correction to this file was done on 28-May-2021, based on the information previously received on 20-MAY-2021 following change was made: BNT162B2 was coded as co-suspect product in the product tab (previously coded as Covid-19 Vaccine). Most recent follow-up information received from consumer via Canada HA on 05-Jul-2021 incorporated above includes: Added new events. Most recent follow-up information received from the other health professional via Canada Health Authority (CA-HEALTHCANVIG-E2B_04149686) incorporated above includes: 07-SEP-2021 Suspect product, product attributes and New events added. Atenolol was considered as additional suspect. Events Chills, Pyrexia and Vomiting were added additionally. Most recent follow-up information received from other health professional via Canada HA on 25-Nov-2021 incorporated above includes: suspect product details, event attributes and narrative updated. Further company follow-up with the Physician is not possible.

Apixaban(ELIQUIS) is under agreement with Bristol-Myers Squibb.

Follow-up (22Nov2021): This is a follow-up report received from a contactable healthcare professional from Regulatory Authority via License Party (AstraZeneca). Regulatory number: E2B_04149686 (Health Canada). Other Case identifier(s): CA-Atnahs Limited-ATNAHS20211124694 (Atnahs Limited), ATNAHS20211124694 (Atnahs Limited), CA-AstraZeneca-2021A848073 (AstraZeneca).

This spontaneous case (MFR no: E2B_04149686) was reported by a healthcare professional in Canada to Health Canada and was received by Atnahs on 22/Nov/2021. This case refers to a 91-year-old female patient who experienced cerebral haemorrhage, cerebrovascular accident, chills, craniocerebral injury, fall, haemorrhagic stroke, pyrexia, subarachnoid haemorrhage, subdural haemorrhage and vomiting during therapy with atenolol at a dose of 50mg administered twice daily, administered orally in tablet form for the treatment of atrial fibrillation. This case was considered serious due to the reactions being of medical significance, the patient requiring hospitalisation and resulting in death. Co-suspect medications were reported as Eliquis film coated tablets administered at a dose of 5mg twice daily for the treatment of cerebrovascular accident prophylaxis and Pfizer-biontech COVID-19 vaccine vial contains 6 doses of 0.3ml after dilution for the treatment of COVID-19 immunisation administered once in total. There were no reported concomitant medications. The patients medical history was not reported. On an unknown date the patient began oral therapy with atenolol tablets administered at a dose of 50mg twice daily for the treatment of atrial fibrillation. On an unknown date the patient experienced cerebral haemorrhage, cerebrovascular accident, chills, craniocerebral injury, fall, haemorrhagic stroke, pyrexia, subarachnoid haemorrhage, subdural haemorrhage, and vomiting. Action taken with atenolol was reported as unknown. At the time of the report, the outcome of all reactions was reported as fatal. No further information was available. Report received by AstraZeneca/MedImmune from Atnahs on 29-Nov-2021.CAUSE OF DEATH: CEREBRAL HAEMORRHAGE CAUSE OF DEATH: CEREBROVASCULAR ACCIDENT CAUSE OF DEATH: CHILLS CAUSE OF DEATH: CRANIOCEREBRAL INJURY CAUSE OF DEATH: FALL CAUSE OF DEATH: HAEMORRHAGIC STROKE CAUSE OF DEATH: PYREXIA CAUSE OF DEATH: SUBARACHNOID HAEMORRHAGE CAUSE OF DEATH: SUBDURAL HAEMORRHAGE CAUSE OF DEATH: VOMITING CEREBRAL HAEMORRHAGE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CEREBROVASCULAR ACCIDENT - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CHILLS - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes CRANIOCEREBRAL INJURY - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes FALL - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes HAEMORRHAGIC STROKE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes PYREXIA - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes SUBARACHNOID HAEMORRHAGE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes SUBDURAL HAEMORRHAGE - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes VOMITING - MEDICAL CONFIRMATION BY HEALTH PROFESSIONAL: Yes.

AstraZeneca Comment: This case concerns a 91 year old female patient with reported 10 Serious Fatal events in association with Atenolol. Vomiting is listed in the company core data sheet of suspect drug. However, as the serious adverse event is reported with the seriousness criteria of Death the events is considered unlisted. Events of Cerebral haemorrhage, Cerebrovascular accident, Craniocerebral injury, Haemorrhagic stroke, Subarachnoid haemorrhage and Subdural haemorrhage could be associated with each other and further be confounding factor for the event of Vomiting. Event of Fall could be contributory risk factor for the event of Subarachnoid haemorrhage and Subdural haemorrhage. Due to limited information on relevant medical history, concurrent diseases, concomitant medications, exact start date of suspect drug, exact start date and circumstances leading to the event, complete etiologic and diagnostic workup (Complete Blood count, Imaging studies, Neurological examination) evaluation did not find evidence to suggest a causal relationship between Events and suspect Drug.

The reporter considered the events Cerebral haemorrhage, Cerebrovascular accident, Chills, Craniocerebral injury, Fall, Haemorrhagic stroke, Pyrexia, Subarachnoid haemorrhage, Subdural haemorrhage, Vomiting related to ATENOLOL.

Atenolol is under agreement with AstraZeneca.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Pfizer comment: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 and Atenolol to the development of reported events cannot be fully excluded. Medical history of previous stroke may provided a plausible alternative explanation for the events of Stroke and Cerebral bleeding. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
BMS medical evaluation comment: This 91 years old patient died due to fall, craniocerebral injury leading to subarachnoid hhaemorrhage, subdural haemorrhage and hemorrhagic stroke after receiving apixaban therapy for atrial fibrillation. Based on the elderly age and nature of the reported events fall leading to craniocerebral injury is considered not related to suspect therapy. Although fall contributed, considering the anticoagulant nature of suspect therapy, its causal role in the reported bleeding events are considered possible.

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Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Middle cerebral artery stroke	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
20170426 CCYYMMDD		
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Atrial fibrillation	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
	Yes	
Comments (B.1.7.1g)		
on Eliquis 5mg oral 2x/day and AFenolol 50mg oral daily		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	TIA	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
2011 CCYY		
Comments (B.1.7.1g)		
Recurrent TIA in 2011		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Coronary artery disease	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
2013 CCYY		
Comments (B.1.7.1g)		
crestor 5mg oral daily		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemorrhagic stroke	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Chills	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Pyrexia	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

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MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Vomiting	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Subarachnoid haemorrhage	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Subdural haemorrhage	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Craniocerebral injury	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Fall	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Cerebral bleeding	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Hemorrhagic stroke	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
26.0	Stroke	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

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Past drug therapy (B.1.8)

Drug name (B.1.8a)
COVID-19 VACCINE

Start date (B.1.8c)	End date (B.1.8e)

Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
26.0	COVID-19 immunization

Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)

Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)

Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)

MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)

MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

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Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		