Sind COVID-19-Impfstoffe sicher?

- Kennt man die Langzeitwirkungen?
- Treten nur vereinzelt leichte Nebenwirkungen auf?
- Gibt es keine schwerwiegenden Nebenwirkungen oder Todesfälle?
- Sind die Studien zur Sicherheit und Wirksamkeit abgeschlossen?

Schon gewusst?

Kritische Experten und wissenschaftliche Studien werden nicht nur von den großen Medien verschwiegen, sondern zusätzlich auf den Internetplattformen zensiert / gelöscht ohne, dass Sie es mitbekommen?

Kennen Sie die EMA Datenbank für **Nebenwirkungen?**



EudraVigilance - Europäische Datenbank gemeldeter Verdachtsfälle von Arzneimittelnebenwirkungen

Offizielle Datenbank der europäischen Arzneimittel Agentur (EMA) www.adrreports.eu Weitere Datenbanken: VAERS https://vaers.hhs.gov oder WHO: www.vigiaccess.org

- Steht bei Ihnen bald eine
 Entscheidung zum (Nach)
 Impfen an oder sehen Sie sich
 demnächst dazu gezwungen?
- Hätten Sie gerne, dass Ihre Kinder, Enkel oder Ihre Mitarbeiter geimpft würden?
- Geht es Ihnen seit der Impfung nicht mehr gut und niemand weiß warum?
- Sind Sie Arzt oder Journalist und haben sich bisher nicht umfangreich informiert?

- Informieren Sie sich jetzt direkt bei der EMA oder schauen Sie sich die riesige
- Anzahl bereits gemeldeter Verdachtsfälle mit tödlichem Ausgang im Anhang an!
- Sie können jeden einzelnen Eintrag selbst bei der EMA anschauen und prüfen!
- Nehmen Sie sich Zeit und machen Sie einen Vergleich mit früheren Impfungen!

Niemand wird später sagen können, sie/er hat von nichts gewusst!

Überprüfung der Sicherheit von Covid-19-Impfstoffen

Bedingte Zulassung der Impfstoffe

Alle 4 in der EU verfügbaren Covid-19-Impfstoffe haben durch die europäischen Arzneimittel-Agentur (EMA) eine **bedingte Zulassung für ein Jahr** erhalten. Dafür gelten u.a. folgende Regeln:

- wenn der Vorteil der sofortigen Verfügbarkeit des Arzneimittels das Risiko weniger umfangreicher Daten als normalerweise erforderlich überwiegt
- eine positive **Nutzen-Risiko-Bilanz** des Produkts, d.h. der Nutzen für die öffentliche Gesundheit durch die sofortige Verfügbarkeit des Arzneimittels auf dem Markt überwiegt die **Risiken**, die aufgrund der vorgesehenen **Nachreichung** weiterer Daten bestehen
- der Antragsteller legt umfassende Daten zu einem späteren Zeitpunkt vor

Quelle: Paul-Ehrlich-Institut, www.pei.de/DE/newsroom/dossier/coronavirus/coronavirus-inhalt.html (FAQ / Was ist eine bedingte Zulassung?)

Meldung und Erfassung von Verdachtsfällen von Impfkomplikationen

Die Meldung von Verdachtsfällen von Nebenwirkungen wird i.d.R. von Ärzten oder Apothekern durchgeführt. Sie können auf verschiedene Arten auch von Patienten direkt gemeldet werden. In Deutschland ist die zuständige Behörde für die Überwachung das Paul-Ehrlich-Institut. Diese führt für alle seit 2000 gemeldeten Fälle die Datenbank mit Verdachtsfällen von Impfkomplikationen (DB-UAW, www.pei.de/db-uaw)

Die Meldungen zu Covid-19-Impfstoffen sind dort noch nicht enthalten! Diese werden derzeit in Form von Sicherheitsberichten unter www.pei.de/sicherheitsbericht veröffentlicht. Außerdem erfolgt eine Übermittlung der deutschen Daten an die Europäische Arzneimittel-Agentur, die in einer eigenen Datenbank unter www.adrreports.eu die Daten aller europäischen Arzneimittelbehörden zusammenführt.

Vollständigkeit der Meldungen

Schätzungen zufolge liegen die Melderaten bei nur etwa sechs Prozent aller unerwünschten Arzneimittelwirkungen und bei fünf bis zehn Prozent für schwere Nebenwirkungen.

Quelle: Paul-Ehrlich-Institut, www.pei.de/SharedDocs/Downloads/DE/newsroom/bulletin-arzneimittelsicherheit/2010/4-2010.pdf (Seite 19)

Außerdem muss man beachten, dass insbesondere bei den Meldungen der nationalen Behörden an die EMA ein erheblicher **Meldeverzug** vorliegt. Beim **Paul-Ehrlich-Institut** waren aus dem Sicherheitsbericht vom 31.08.2021 **nur 37%** der Nebenwirkungen bereits an die EMA **gemeldet**.

Auswertungen der EMA-Datenbank

Die bei der EMA gemeldeten mutmaßlichen Nebenwirkungen kann jeder selbst unter www.adrreports.eu recherchieren. Dazu sind folgende Schritte notwendig:

- 1) https://www.adrreports.eu/de/search_subst.html aufrufen, Disclaimer mit "ok" akzeptieren
- 2) Buchstabe "C" anklicken
- 3) Nach unten blättern bis zu folgenden 4 Einträgen:

COVID-19 MRNA VACCINE MODERNA (CX-024414)

COVID-19 MRNA VACCINE PFIZER-BIONTECH (TOZINAMERAN)

COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)

COVID-19 VACCINE JANSSEN (AD26.COV2.S)

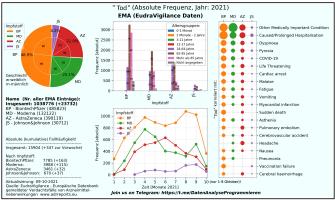
- 4) Gewünschten Impfstoff anklicken --> es erscheinen verschiedene Übersichten zur Auswertung
- 5) Alle Einzelfälle einer bestimmten Kategorie sind einzeln unter Tab "Line Listing" abrufbar und können auch bspw. nach Excel exportiert und dort weiter gefiltert und ausgewertet werden.

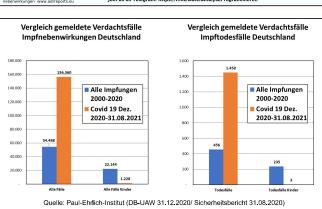
Verdachtsmeldungen Todesfälle nach Covid-Impfungen

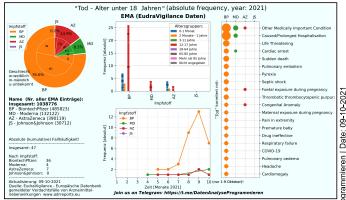
Die folgenden Seiten enthalten alle zu den vier Covid-19-Impfstoffen in der EMA-Datenbank zum jeweiligen Datenstand veröffentlichten Fälle, bei denen als "Outcome - Seriousness Criteria": "Results in Death" angegeben wurde.

Sie können jeden einzelnen Eintrag in der Liste direkt bei der EMA prüfen: Sie finden pro Zeile (Meldung/Fall/Person) unter der Überschrift "ICSR Form" einen QR-Code sowie einen anklickbaren Link, mit dem Sie die jeweilige Meldung in anonymisierter Form direkt als PDF bei der EMA herunterladen können.

Hinweis: Die Server der EMA sind zeitweise sehr stark ausgelastet. Daher kann es auch mal einige Sekunden dauern bis der Download startet oder Sie bekommen eine Fehlermeldung Ihres Browsers. Dann bitte zu einem späteren Zeitpunkt erneut versuch (da es sich um die offiziellen EMA-Server handelt, können wir daran leider nichts ändern).







	BioNTech	AstraZeneca	Moderna	Janssen	Gesamt
Anzahl Impfungen	425.766.347	67.814.642	60.613.246	15.093.951	569.288.186
Todesfälle	7.785	3.461	3.988	670	15.904
Lebensbedrohlich	9.317	7.331	4.402	1102	22.152
Längerer Krankenhausaufenthalt	41.768	24.900	19.213	3732	89.613
Behindernd	17.109	22.695	5.610	1096	46.510
Ernste Nebenwirkungen	187.488	196.679	60.512	10.763	455.442
Alle Fälle mit Nebenwirkungen	485.823	390.119	132.122	30.712	1.038.776

Datenstand 09,10,2021 | Quellen: Nebenwirkungen: EMA; Impfzahlen: European center for disease prevention and control, qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html

Hinweis: Wie bereits unter "Vollständigkeit der Meldungen" beschrieben erfolgt für viele Meldungen keine oder eine stark verzögerte Meldung von Nebenwirkungen, so dass die Zahl der tatsächlichen Nebenwirkungen im Verhältnis zu den durchgeführten Impfungen stets deutlich unterschätzt werden



Created by: /t.me/DatenAnalyseProgrammieren | Date: 09-

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
1	EU-EC- 10010254138		2021-10- 07	Non Healthcare Professional	EEA	2 Months - 2 Years	Female	Foetal hypokinesia (n/a - Fatal - <u>Results in Death</u>), Limb malformation (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental])
2	EU-EC-1001024598		2021-10- 07	Healthcare Professional	Non EEA	12-17 Years	Male	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - Results in Death), Ventricular fibrillation (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
3	EU-EC- 10010236495		2021-10- 06	Healthcare Professional	EEA	12-17 Years	Female	ADAMTS13 activity decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenic purpura (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
4	click or scan EU-EC- 1001022709		2021-10- 05	Healthcare Professional	Non EEA	12-17 Years	Female	Acute myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Anaemia (n/a - Fatal - Results in Death), Back pain (n/a - Unknown -), Bone marrow failure (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Object of Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - Results in Death), Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Red blood cell abnormality (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - Results in Death), Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Transplacental]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Transplacental])
5	EU-EC- 10010217879		2021-10- 05	Non Healthcare Professional	EEA	12-17 Years	Female	Sudden death (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
6	click or scan EU-EC- 10010215836		2021-10- 05	Non Healthcare Professional	EEA	0-1 Month	Male	Ascites (n/a - Fatal - <u>Results in Death</u>), Brain oedema (n/a - Fatal - <u>Results in Death</u>), Foetal malformation (n/a - Fatal - <u>Results in Death</u>), Mitral valve atresia (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Transplacental])
7	EU-EC- 10010210329		2021-10- 04	Healthcare Professional	EEA	0-1 Month	Female	Hypoxic-ischaemic encephalopathy (n/a - Fatal - <u>Results in Death</u>), Neonatal anoxia (n/a - Fatal - <u>Results in Death</u>), Neonatal multi-organ failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
8	EU-EC- 10010206309		2021-10- 04	Non Healthcare Professional	EEA	12-17 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])

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#	EU Local Number		Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	LAGE	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
9	elick or scan EU-EC- 10010194286		2021-10- 01	Non Healthcare Professional	Non EEA	12-17 Years	Male	Cardiomegaly (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
10	<u>click or scan</u> EU-EC- 10010193681		2021-10- 01	Healthcare Professional	Non EEA	12-17 Years	Male	Cerebral haemorrhage (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ventricular rupture (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
11	elick or scan EU-EC- 10010180043		2021-09- 30	Healthcare Professional	EEA	12-17 Years	Female	Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - Contraception - Drug withdrawn - [n/a - 21 {DF} - Oral])
12	click or scan		2021-09-	Non Healthcare Professional			Not Specified	Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital Anomaly), Limb malformation (n/a - Fatal - Results in Death, Congenital Anomaly), Limb reduction defect (n/a - Fatal - Results in Death, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
13	EU-EC- 10010166958		2021-09- 29	Healthcare Professional	EEA	12-17 Years	Male	Pulmonary oedema (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
14				Non Healthcare Professional	Non EEA	12-17 Years	Male	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Pulmonary sepsis (n/a - Fatal - Results in Death, Other Medically Important Condition), Septic shock (n/a - Fatal - Results in Death, Other Medically Important Condition), Septic shock (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
15	EU-EC- 10010127333		2021-09- 24	Healthcare Professional	Non EEA	12-17 Years	Male	Adverse event following immunisation (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular])
16	elick or scan EU-EC- 10010093552		2021-09- 22	Non Healthcare Professional	EEA	12-17 Years	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
17	EU-EC- 10010073173		2021-09- 20	Healthcare Professional	EEA	2 Months - 2 Years	Not Specified	Foetal exposure during pregnancy (14d - Fatal - <u>Results in Death</u>), Heart disease congenital (14d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
18	elick or scan EU-EC- 10010027057		2021-09- 16	Non Healthcare Professional	Non EEA	12-17 Years	Male	Circulatory collapse (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Respiratory failure (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

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#	EU Local Number	ICSR Form	Gateway	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List P1 (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
19	EU-EC- 10010010062			Healthcare Professional	Non EEA	12-17 Years	Female	Cerebrovascular accident (1d - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular])
20	click or scan EU-EC- 10010009963		2021-09- 15	Healthcare Professional	EEA	12-17 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death,</u> Other Medically Important Condition)	COMID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [78d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
21	EU-EC- 10010007112		2021-09- 15	Healthcare Professional	Non EEA	12-17 Years	Male	Adverse event following immunisation (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
22	EU-EC- 10009989870		2021-09- 14	Non Healthcare Professional	EEA	0-1 Month		Anencephaly (n/a - Fatal - Results in Death, Congenital Anomaly), Maternal exposure before pregnancy (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [78d - n/a - n/a])
23	EU-EC- 10009961040		2021-09-	Non Healthcare Professional	EEA	12-17 Years	Male	Pulmonary oedema (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
24	EU-EC- 10009864895			Healthcare Professional	EEA	12-17 Years	Male	Septic shock (26d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])
25	<u>click or scan</u> EU-EC- 10009860999			Healthcare Professional	EEA	12-17 Years	Male	Leukaemia (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
26	elick or scan EU-EC- 10009819192			Healthcare Professional	EEA	12-17 Years	Male	Sudden death (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
27	<u>click or scan</u> EU-EC- 10009817992		27	Healthcare Professional	EEA	12-17 Years	Male	Pulmonary embolism (n/a - Fatal - Results in Death), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
28	click or scan EU-EC- 10009815542		2021-08- 27	Non Healthcare Professional	Non EEA	12-17 Years	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
29	elick or scan EU-EC- 10009800757		2021-08- 26	Non Healthcare Professional	Non EEA	2 Months - 2 Years	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diet refusal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Emotional distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Failure to thrive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heatic enzyme increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary]) COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Transplacental]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
30	EU-EC- 10009789688	ELECTRICAL SECTION SEC	2021-08- 25	Non Healthcare Professional	Non EEA	0-1 Month		Foetal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Hydrocephalus (n/a - Fatal - Results in Death, Congenital Anomaly)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Transplacental])
31	EU-EC- 10009749988		2021-08- 20	Healthcare Professional	EEA	12-17 Years	Female	Arrhythmia (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
32	EU-EC- 10009747324	国为1998年4	2021-08- 20	Healthcare Professional	EEA	12-17 Years	Male	Disseminated intravascular coagulation (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary haemorrhage (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])
33	EU-EC- 10009743215		2021-08- 20	Non Healthcare Professional	Non EEA	12-17 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
34	EU-EC- 10009668303		2021-08- 12	Healthcare Professional	EEA	12-17 Years	Female	Cardiac arrest (1d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])
35	EU-EC- 10009631536		2021-08- 09	Non Healthcare Professional	Non EEA	0-1 Month		Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Premature baby (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR])
36	EU-EC- 10009528413		2021-07- 29	Non Healthcare Professional	Non EEA	12-17 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
37	EU-EC- 10009340528		2021-07- 12	Healthcare Professional	EEA	0-1 Month		Antibody test abnormal (n/a - Fatal - <u>Results in Death</u>), Isoimmune haemolytic disease (n/a - Fatal - <u>Results in Death</u>), Rhesus antibodies positive (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
38	click or scan EU-EC- 10009321122		2021-07- 09	Non Healthcare Professional	Non EEA	12-17 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown])

<u>r mei</u>	Itered by "Seriousness Criteria": "Results in Death"										
#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])		
39	click or scan EU-EC- 10009320743		2021-07- 09	Healthcare Professional	EEA	0-1 Month	Male	Growth retardation (n/a - Fatal - Results in Death), Premature delivery (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]), [ATENOLOL, ATENOLOL BP] (S - Cardiac valve disease - Not applicable - [n/a - n/a - Oral])		
40	<u>click or scan</u> EU-EC- 10009305404		2021-07- 08	Non Healthcare Professional	Non EEA	12-17 Years		Cardiomegaly (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pericardial effusion (n/a - Fatal - Results in Death)	- Not applicable - [n/a - 1 {DF} - Transplacental]), [ATENOLOL, ATENOLOL BP] (S - Cardiac valve disease - Not applicable - [n/a - n/a - Oral]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Transplacental])		
41	EU-EC- 10009213103		2021-06- 30	Healthcare Professional	EEA	0-1 Month	Female	Foetal death (n/a - Fatal - <u>Results in Death</u>), Generalised oedema (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Transplacental])		
42	EU-EC- 10009206279		2021-06- 30	Non Healthcare Professional	Non EEA	2 Months - 2 Years	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Maternal exposure during breast feeding (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a ; - n/a - Transmammary])		
43	click or scan EU-EC- 10009129480		2021-06- 24	Non Healthcare Professional	Non EEA	12-17 Years	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved -), Completed suicide (n/a - Fatal - Results in Death), Decreased appetite (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Not Recovered/Not Resolved -), Hacadache (n/a - Not Recovered/Not Resolved -), Hypersommia (n/a - Not Recovered/Not Resolved -), Illness (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Unknown -)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Transmammary]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular - More in ICSR]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])		
44	EU-EC- 10008822508		2021-05- 28	Healthcare Professional	Non EEA	0-1 Month	Male	Death (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition), Meconium aspiration syndrome (n/a - Unknown - Other Medically Important Condition), Premature baby (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR])		
45	EU-EC- 10008609552		2021-05- 11	Healthcare Professional	EEA	0-1 Month	Male	Death (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a])		
46	elick or scan EU-EC- 10008557015		2021-05- 06	Healthcare Professional	EEA	12-17 Years		Cardiac arrest (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])		
47	EU-EC- 10008490019		2021-04- 30	Healthcare Professional	Non EEA	12-17 Years	Female	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])		

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
48	click or scan EU-EC- 10010267782		2021-10- 08	Healthcare Professional	EEA	18-64 Years	Male	Arterial thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Balance disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Cerebral palsy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Impaired self-care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
49	EU-EC- 10010267704		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Asthenia (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death), Cardiac tamponade (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Pericardial effusion (n/a - Fatal - Results in Death), Physical deconditioning (n/a - Fatal - Results in Death), Pulseless electrical activity (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
50	EU-EC- 10010267574		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Other Medically Important Condition), Volvulus (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
51	EU-EC- 10010267572		2021-10- 08	Healthcare Professional	EEA	65-85 Years	Female	Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
52	EU-EC- 10010267508		2021-10- 08	Non Healthcare Professional	EEA	More than 85 Years	Iviale	Asthenia (21d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (21d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (21d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (21d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory distress (21d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular])
53	EU-EC- 10010267302		2021-10- 08	Non Healthcare Professional	Non EEA	18-64 Years	Male	Anger (n/a - Fatal - Results in Death, Life Threatening, Disabling), Bipolar disorder (n/a - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Completed suicide (n/a - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Hostility (n/a - Fatal - Results in Death, Life Threatening, Disabling), Personality change (n/a - Fatal - Results in Death, Life Threatening, Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
54	<u>click or scan</u> EU-EC- 10010267299		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Female	Respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
55	<u>click or scan</u> EU-EC- 10010266993		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Male	Cerebellar infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
56	EU-EC- 10010266989		2021-10- 08	Non Healthcare Professional	Non EEA	Not Specified	Female	Abdominal pain upper (n/a - Unknown -), Aortic aneurysm rupture (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])

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#	Number	ICSR Form	Gateway	Primary Source Qualification	for		Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
57	EU-EC- 10010266893		2021-10- 08	Healthcare Professional		More than 85 Years	Female	Blood pressure decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Metabolic acidosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown -), Physical deconditioning (n/a - Unknown -), Pyrexia (n/a - Unknown -), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
58	EU-EC- 10010266892			Healthcare Professional		65-85 Years	Male	Death (n/a - Fatal - Results in Death), Immunisation (n/a - Unknown -), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
59				Healthcare Professional		More than 85 Years	Female	Renal failure (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
60	EU-EC- 10010266814		2021-10- 08	Healthcare Professional		More than 85 Years	Female	Cholangitis acute (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
61	<u>click or scan</u> EU-EC- 10010266810		2021-10- 08	Non Healthcare Professional	EEA	65-85 Years		Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])
62	EU-EC- 10010266765			Healthcare Professional	EEA	65-85 Years	Male	Cardiac arrest (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular])
63	click or scan		2021-10- 08	Non Healthcare Professional	EEA	65-85 Years	Female	Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Herpes zoster (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
64	EU-EC- 10010266720		2021-10- 08	Healthcare Professional	EEA	18-64 Years	Male	Obstructive airways disorder (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
65	elick or scan EU-EC- 10010266713			Healthcare Professional	EEA	18-64 Years	Male	Venous thrombosis (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
66	click or scan EU-EC- 10010266696			Healthcare Professional		65-85 Years	Male	Death (1d - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d5mL - Intramuscular]), ZYPREXA 5 MGCOATED TABLETS [OLANZAPINE] (S - Depression - Not applicable - [n/a - 5mg - Oral]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (S - Depression - Not applicable - [n/a - 150mg - Oral])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
6	click or scan EU-EC- 10010266683	国1299469453457	2021-10- 08	Non Healthcare Professional	EEA	65-85 Years	Male	Cardiac arrest (1d - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
6	EU-EC- 10010266680		2021-10- 08	Healthcare Professional	EEA	65-85 Years	Male	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
6	EU-EC- 10010266645			Healthcare Professional	EEA	18-64 Years	Female	Death (1d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
7	elick or scan EU-EC- 10010266615		2021-10- 08	Healthcare Professional	EEA	18-64 Years	Female	Anaplastic thyroid cancer (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
7	click or scan EU-EC- 10010266569		2021-10- 08	Healthcare Professional	EEA	18-64 Years	Male	Cerebral haemorrhage (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])
7.	click or scan EU-EC- 10010266528		2021-10- 08	Healthcare Professional	EEA	65-85 Years	Male	Arteriosclerosis coronary artery (n/a - Unknown - Results in Death, Other Medically Important Condition), Cardiac hypertrophy (n/a - Unknown - Results in Death, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - Results in Death, Other Medically Important Condition), Coronary artery thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Heparin-induced thrombocytopenia test positive (n/a - Unknown - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])
7.	EU-EC- 10010266022			Healthcare Professional	Non EEA	65-85 Years	Female	Cardiac failure (n/a - Fatal - Results in Death), Eyelid haematoma (n/a - Unknown -), Fall (n/a - Unknown -), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Orbital swelling (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
7	elick or scan EU-EC- 10010266014		2021-10- 08	Non Healthcare Professional	Non EEA	Not Specified	Female	Death (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
7	click or scan EU-EC- 10010265639		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])

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#	EU Local Number		Gateway	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
76	<u>click or scan</u> EU-EC- 10010265635		2021-10- 08	Non Healthcare Professional	Non EEA	18-64 Years	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])
77	click or scan EU-EC- 10010265524		2021-10-	Non Healthcare Professional	EEA	18-64 Years		COVID-19 (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - 2{DF} - n/a])
78	EU-EC- 10010265381		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years		Cardiac arrest (1d - Fatal - Results in Death), Myocardial ischaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
79	elick or scan EU-EC- 10010265185			Healthcare Professional	EEA	65-85 Years	Male	C-reactive protein increased (n/a - Fatal - Results in Death), Chills (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Feeling cold (n/a - Fatal - Results in Death), Castrointestinal haemorrhage (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Mausea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Skin discolouration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
80	<u>click or scan</u> EU-EC- 10010265064			Healthcare Professional	Non EEA	65-85 Years		Asthenia (n/a - Fatal - <u>Results in Death</u>), Dysarthria (n/a - Fatal - <u>Results in Death</u>), Facial paralysis (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
81	<u>click or scan</u> EU-EC- 10010264635			Healthcare Professional	Non EEA	18-64 Years	Male	Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
82	click or scan EU-EC- 10010264519		2021-10-	Non Healthcare Professional	EEA	65-85 Years	Female	General physical health deterioration (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])

#		EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
83		click or scan EU-EC- 0010264324		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	I vale	Alanine aminotransferase increased (n/a - Unknown -), Albumin globulin ratio decreased (n/a - Unknown -), Altered state of consciousness (n/a - Fatal - Results in Death), Angina pectoris (n/a - Fatal - Results in Death), Other Medically Important Condition), Aspartate aminotransferase increased (n/a - Unknown -), Blood alkaline phosphatase increased (n/a - Unknown -), Blood creatine increased (n/a - Unknown -), Blood glucose increased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood potassium increased (n/a - Unknown -), Blood pressure immeasurable (n/a - Unknown -), Blood urea increased (n/a - Unknown -), Brain natriuretic peptide increased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), Cardiac failure (n/a - Fatal - Results in Death), Chardiac valve disease (n/a - Unknown -), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Chest pain (n/a - Fatal - Results in Death), Cyanosis (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Haematocrit decreased (n/a - Unknown -), Haemoglobin decreased (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mean cell haemoglobin concentration decreased (n/a - Unknown -), Myocardial ischaemia (n/a - Fatal - Results in Death), Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - Results in Death), Physical deconditioning (n/a - Unknown -), Platelet count decreased (n/a - Unknown -), Protein total decreased (n/a - Unknown -), Prothrombin time ratio increased (n/a - Unknown -), Red blood cell count decreased (n/a - Unknown -), Troponin T increased (n/a - Unknown -), White blood cell count increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - 1ntramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (I - n/a - Not applicable - [n/a - n/a - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (I - n/a - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - 1ntramuscular]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S Immunisation - Not applicable - [n/a - n/a - Unknown])
84		EU-EC- 0010264151		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years		Bacterial sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown -), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
85	;	EU-EC- 0010264058		2021-10- 08	Non Healthcare Professional	EEA	18-64 Years	Male	Atherosclerotic plaque rupture (n/a - Fatal - Results in Death), Coronary artery occlusion (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death), Palpitations (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Resuscitation (n/a - Fatal - Results in Death), Visual impairment (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - [2]]
86	,	EU-EC- 0010263980		2021-10- 08	Non Healthcare Professional	Non EEA	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Drug interaction (n/a - Unknown - Results in Death), Vaccination failure (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (I - n/a - Not applicable - [n/a - n/a - n/a]), [LISINOPRIL, LISINOPRIL ANHYDROUS, LISINOPRIL DIHYDRATE] (I - n/a - Not applicable - [n/a - n/a - Oral])
87	· •	EU-EC- 0010263937		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Female	Aortic dissection (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
88		EU-EC- 0010263899		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Female	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
89	, -	EU-EC- 0010263884		2021-10- 08	Non Healthcare Professional	Non EEA	Not Specified	Female	Thrombosis (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
90	٠ '	click or scan EU-EC- 0010263819		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Male	Chills (n/a - Unknown - Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Other Medically Important Condition), Retching (n/a - Unknown - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date		Primary Source Country for Regulatory Purposes	Croun	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
91	click or scan EU-EC- 10010263685		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years		Angiogram pulmonary abnormal (n/a - Fatal - Results in Death, Other Medically Important Condition), Aortic dilatation (n/a - Fatal - Results in Death, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - Results in Death, Other Medically Important Condition), Coverbal small vessel ischaemic disease (n/a - Fatal - Results in Death, Other Medically Important Condition), Computerised tomogram head abnormal (n/a - Fatal - Results in Death, Other Medically Important Condition), Computerised tomogram head abnormal (n/a - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death, Other Medically Important Condition), Lacunar infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Lung infiltration (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial strain (n/a - Fatal - Results in Death, Other Medically Important Condition), Pain (n/a - Fatal - Results in Death, Other Medically Important Condition), Pain (n/a - Fatal - Results in Death, Other Medically Important Condition), Palmonary embolism (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 antibody test positive (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Other Medically Impor	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
92	click or scan EU-EC- 10010263661		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Arteriosclerosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown -), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown -), Diarrhoea (21d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Joint swelling (n/a - Unknown -), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paralysis (n/a - Unknown - Other Medically Important Condition), Paralysis (n/a - Unknown - Other Medically Important Condition), Prepheral swelling (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paral - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Weight decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Weight decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a - Intramuscular])
93	elick or scan EU-EC- 10010263658		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Female	Cardiac failure congestive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
94	click or scan EU-EC- 10010263642		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years		Abdominal pain upper (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute coronary syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebrovascular disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
95	elick or scan EU-EC- 10010263641		08	Healthcare Professional	Non EEA	18-64 Years	Female	Cyanosis (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
96	EU-EC- 10010263627		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u> . Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number		Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
97	EU-EC- 10010263624		2021-10- 08	Non Healthcare Professional	Non EEA	65-85 Years	Male	Cerebrovascular accident (n/a - Fatal - Results in Death), Immunisation (n/a - Unknown -), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
98	EU-EC- 10010263571		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Product administered at inappropriate site (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
99	<u>click or scan</u> EU-EC- 10010263570		2021-10- 08	Non Healthcare Professional	Non EEA	Not Specified	Female	Blindness (n/a - Unknown - Other Medically Important Condition), Breast cancer (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death , Other Medically Important Condition), Hepatic cancer (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
100				Healthcare Professional	EEA	65-85 Years	Male	Acute pulmonary oedema (n/a - Fatal - Results in Death , Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - Results in Death , Other Medically Important Condition), Cardiagenic shock (n/a - Fatal - Results in Death , Other Medically Important Condition), Chronic kidney disease (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
101	EU-EC- 10010263561			Healthcare Professional	Non EEA	18-64 Years	Male	Asphyxia (n/a - Fatal - Results in Death), Body temperature increased (n/a - Unknown -), Cardiac failure acute (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Pulse absent (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
102	click or scan		08	Healthcare Professional	Non EEA	65-85 Years	Male	Cough (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Nasopharyngitis (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
103	10010263352		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	Asthenia (n/a - Fatal - <u>Results in Death</u>), Cough (11d - Fatal - <u>Results in Death</u>), Fatigue (n/a - Fatal - <u>Results in Death</u>), Nausea (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
104	EU-EC- 10010263351		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Male	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
105	click or scan		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Male	Dyspnoea (n/a - Fatal - <u>Results in Death</u>), Fatigue (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
106	EU-EC- 10010263347		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])

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#	EU Local Number	ICSK FORM	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
107	EU-EC- 10010263343		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	Chills (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Throat irritation (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
108			2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Male	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
109	EU-EC- 10010263322		2021-10- 08	Non Healthcare Professional	EEA	65-85 Years	Female	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
110	EU-EC- 10010263192		2021-10- 08	Healthcare Professional	EEA	65-85 Years	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])
111	EU-EC- 10010263016		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Decreased appetite (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
112	click or scan EU-EC- 10010263014		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Female	Loss of consciousness (5min - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
113	EU-EC- 10010262742		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Female	Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
114	EU-EC- 10010262539			Non Healthcare Professional	EEA	More than 85 Years	Male	Death (0d - Fatal - <u>Results in Death</u>), Hemiplegia (8d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
115	EU-EC- 10010261824		2021-10- 08	Non Healthcare Professional	Non EEA	18-64 Years	Female	Thrombocytopenia (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
116	click or scan		2021-10- 08	Healthcare Professional	EEA	18-64 Years	Male	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Death (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Source Qualification	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
117				Healthcare Professional	Non EEA	65-85 Years	Male	Atrioventricular block complete (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Conduction disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
118	EU-EC- 10010261082		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	Anosmia (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>), Tonsillitis (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
119	<u>click or scan</u> EU-EC- 10010260654		2021-10- 08	Non Healthcare Professional	Non EEA	18-64 Years	Female	Abdominal distension (1d - Recovered/Resolved -), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (n/a - Recovered/Resolved -), Dizziness (n/a - Unknown -), Haemorrhagic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown -), Ischaemic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Migraine (n/a - Unknown -), Nausea (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Retching (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
120	EU-EC- 10010260648		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
121	elick or scan EU-EC- 10010260602		2021-10- 08	Healthcare Professional	EEA	More than 85 Years	Female	COVID-19 (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
122	EU-EC- 10010260531		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Musculoskeletal stiffness (n/a - Fatal - Results in Death, Other Medically Important Condition), Nausea (n/a - Fatal - Results in Death, Other Medically Important Condition), Otitis media (n/a - Fatal - Results in Death, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Thunderclap headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
123	EU-EC- 10010259999		2021-10- 08	Non Healthcare Professional	Non EEA	Not Specified	Not Specified	Rash (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
124	elick or scan EU-EC- 10010259995		08	Healthcare Professional	Non EEA	18-64 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved -), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
125	click or scan EU-EC- 10010259987		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Female	Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malignant ascites (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary hypertension (n/a - Fatal - Results in Death), Right ventricular failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
126	EU-EC- 10010259963		2021-10- 08	Healthcare Professional	Non EEA	More than 85 Years	Female	Acute myeloid leukaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])

Filtered by "Seriousness Criteria": "Results in Death"

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
12	click or scan EU-EC- 10010259866		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Cardiac failure (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thyrotoxic crisis (41d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
12	EU-EC- 10010259733	(E) (78 MS.#5.455)	08	Healthcare Professional	Non EEA	More than 85 Years	Male	Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
12	EU-EC- 10010259630		2021-10- 08	Healthcare Professional	EEA	More than 85 Years	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
13	10010259526		2021-10- 08	Non Healthcare Professional	EEA	More than 85 Years	Female	Cardiac arrest (n/a - Fatal - Results in Death , Life Threatening, Other Medically Important Condition), Erythema (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death , Other Medically Important Condition), Head injury (n/a - Fatal - Results in Death , Other Medically Important Condition) Syncope (n/a - Fatal - Results in Death , Other Medically Important Condition)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Product used for unknown indication - n/a - [n/a - n/a - Intramuscular]), ELIQUIS 5 MG [APIXABAN] (S - Atrial fibrillation - Unknown - [n/a - n/a - Oral]), ELIQUIS [APIXABAN] (S - Cerebrovascular accident prophylaxis - Unknown - [n/a - n/a - Oral]), [AMIODARONE, AMIODARONE - HYDROCHLORIDE] (S - Atrial fibrillation - Unknown - [n/a - n/a - Oral]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (S - Atrial fibrillation - Unknown - [n/a - n/a - Oral]), [CILOST AZOL] (S - Arteriosclerosis - Unknown - [n/a - n/a - Oral]), [METHYLPREDNISOLONE] (S - Myalgia - n/a - [n/a - n/a - Unknown)], [ROSUVAST ATIN] (S - Arteriosclerosis - Unknown - [n/a - n/a - Oral])
13	EU-EC- 10010259521		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	Interstitial lung disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
13			2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	Sudden death (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
13	click or scan EU-EC- 10010259366		2021-10- 08	Non Healthcare Professional	Non EEA	65-85 Years	Male	Immunisation (n/a - Unknown -), Off label use (n/a - Unknown -), Sepsis (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
13	elick or scan EU-EC- 10010259329		2021.10	Healthcare Professional	Non EEA	18-64 Years	Female	Subarachnoid haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - Intramuscular])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Croup	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
135	EU-EC- 10010259224		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Chest pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Immunisation (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
136	click or scan EU-EC- 10010259191			Healthcare Professional	Non EEA	18-64 Years	Male	Haematemesis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
137	click or scan EU-EC- 10010258974		2021-10-	Healthcare Professional	Non EEA	65-85 Years	Male	Haemophagocytic lymphohistiocytosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular])
138	EU-EC- 10010258968		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Male	Dyspnoea (n/a - Fatal - Results in Death), Skin disorder (n/a - Fatal - Results in Death), Skin death (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S-n/a - Not applicable - [n/a - n/a - Intramuscular])
139	EU-EC- 10010258917		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Male	Death (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular])
140	EU-EC- 10010258723		2021-10- 08	Non Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - Results in Death), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
141	EU-EC- 10010258701		2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	Female	Arrhythmia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - n/a])
142	EU-EC- 10010258675		2021-10- 08	Non Healthcare Professional	Non EEA	18-64 Years	Female	Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
143	EU-EC- 10010258634	IEI SON BOOK (ALCO)	08	Healthcare Professional	Non EEA	65-85 Years	Female	Dyspnoea (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
144	EU-EC- 10010258560		2021-10- 08	Healthcare Professional	EEA	Not Specified	Female	Brain neoplasm (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
145	EU-EC- 10010258504	具数据	2021-10- 08	Healthcare Professional	Non EEA	65-85 Years	iviaie	Atrial fibrillation (n/a - Fatal - Results in Death, Other Medically Important Condition), Bradycardia (n/a - Unknown - Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition) Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
146	EU-EC- 10010258417		2021-10- 08	Non Healthcare Professional	Non EEA	18-64 Years	Male	Cough (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
147	click or scan EU-EC- 10010258259		2021-10- 08	Healthcare Professional	Non EEA	18-64 Years	Female	Body temperature normal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	
148	elick or scan EU-EC- 10010257897		2021-10- 08	Non Healthcare Professional	EEA	65-85 Years	Female	Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])
149	EU-EC- 10010257725		2021-10- 08	Non Healthcare Professional	EEA	18-64 Years	Male	Back pain (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
150	EU-EC- 10010257688		2021-10- 08	Healthcare Professional	EEA	65-85 Years	Male	Acute leukaemia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
151	<u>click or scan</u> EU-EC- 10010257574		2021-10- 08	Non Healthcare Professional	EEA	18-64 Years	Male	Feeling cold (n/a - Fatal - <u>Results in Death</u>), Haematuria (n/a - Fatal - <u>Results in Death</u>), Heart rate increased (n/a - Fatal - <u>Results in Death</u>), Hyperhidrosis (n/a - Fatal - <u>Results in Death</u>), Hyperhidrosis (n/a - Fatal - <u>Results in Death</u>), Pallor (n/a - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
152	<u>click or scan</u> EU-EC- 10010256603		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Adverse event following immunisation (n/a - Fatal - Results in Death), Chest pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
153	<u>click or scan</u> EU-EC- 10010256584		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Cerebral venous thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular])
154	elick or scan EU-EC- 10010256536		2021-10- 07	Healthcare Professional	EEA	Not Specified	Female	Drug interaction (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Myelodysplastic syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (I - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]), OLAPARIB [OLAPARIB] (I - BRCA1 gene mutation, Ovarian cancer - Drug withdrawn - [1mo - n/a - Oral])

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#	Number	CSK FORM	Gateway	Primary Source	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
155	EU-EC- 10010256223		07	Non Healthcare Professional	Non EEA	18-64 Years	Female	Fatigue (5d - Recovered/Resolved -), Pyrexia (n/a - Fatal - <u>Results in Death</u>), Vaccination site pain (5d - Recovered/Resolved -)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular])
156	EU-EC- 10010256012		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
157	EU-EC- 10010255989			Healthcare Professional	Non EEA	65-85 Years	Male	Road traffic accident (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
158	EU-EC- 10010255839			Healthcare Professional	Non EEA	18-64 Years	Female	Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
159	EU-EC- 10010255773			Healthcare Professional	Non EEA	65-85 Years	Male	Arrhythmia (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown -), Drowning (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
160	EU-EC- 10010255735			Healthcare Professional	Non EEA	18-64 Years		Asthenia (n/a - Fatal - Results in Death), Blood glucose abnormal (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Feeling abnormal (n/a - Unknown -), Vomiting (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
161	EU-EC- 10010255598		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Female	Abdominal infection (n/a - Fatal - Results in Death, Other Medically Important Condition), Abdominal pain (2d - Fatal - Results in Death), Fatigue (n/a - Unknown -), Intestinal obstruction (2d - Fatal - Results in Death), Other Medically Important Condition), Multiple organ dysfunction syndrome (1d - Fatal - Results in Death), Other Medically Important Condition), Myalgia (n/a - Unknown -), Pneumonia (2d - Fatal - Results in Death), Other Medically Important Condition), Pyrexia (2d - Fatal - Results in Death), Sepsis (2d - Fatal - Results in Death), Other Medically Important Condition), Septic shock (1d - Fatal - Results in Death), Other Medically Important Condition)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
162	EU-EC- 10010255541		07	Healthcare Professional	Non EEA	65-85 Years	Male	Respiratory distress (n/a - Unknown - Life Threatening, Other Medically Important Condition), Sepsis (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
163	EU-EC- 10010255347		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Deep vein thrombosis (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date		Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])	
16	elick or sear 4 EU-EC- 1001025533		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anisocytosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cher Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Lung opacity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Lung opacity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Right ventricular failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Vigilance www.adrreports.eu Date: 09-10-2021
16	5 Click or scar EU-EC- 1001025524		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years		Anaemia (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Unknown -), Interstitial lung disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatitis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pulmonary fibrosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	ata Source: Eudra
16	elick or scar EU-EC- 1001025508		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Female	Cardiac failure acute (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	rammieren D
16	click or scar EU-EC- 1001025502		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Subarachnoid haemorrhage (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	nAnalyseProg
16	8 click or scar EU-EC- 1001025495	7	2021-10- 07	Non Healthcare Professional	Non EEA	65-85 Years	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown -), Syncope (n/a - Unknown -), Thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vision blurred (n/a - Unknown -)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	tps://t.me/Date
16	1001025488		07	Healthcare Professional	Non EEA	65-85 Years	Female	Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Created by: ht
17	Click or scar EU-EC- 1001025464		2021-10- 07	Non Healthcare Professional	Non EEA	18-64 Years		Asthenia (2d - Fatal - Results in Death), Dyspnoea (2d - Fatal - Results in Death), Pain in extremity (2d - Fatal - Results in Death), Pyrexia (2d - Fatal - Results in Death), Rash (2d - Fatal - Results in Death), Salivary hypersecretion (2d - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])	
17	click or scar		2021-10- 07	Healthcare Professional		65-85 Years	Male	Cardio-respiratory arrest (n/a - Fatal - <u>Results in Death</u>), Decreased appetite (n/a - Not Recovered/Not Resolved -), Hyponatraemia (n/a - Unknown -), Pneumonia (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	

#	EU Local Number		EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
172	EU-EC- 10010254558	即城里 和班首 西班高	2021-10- 07	Healthcare Professional	EEA	More than 85 Years	Female	Pneumonia aspiration (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a])
173	elick or scan EU-EC- 10010254554		2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	remaie	Lymphadenopathy (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
174	elick or scan EU-EC- 10010254504		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Cardio-respiratory arrest (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Marasmus (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
175	click or scan		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Concomitant disease aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
176	EU-EC- 10010254383		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Female	Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thalamus haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
177	EU-EC- 10010254343		2021-10- 07	Non Healthcare Professional	Non EEA	Not Specified	Female	Brain oedema (n/a - Fatal - <u>Results in Death</u>), Cerebral venous sinus thrombosis (n/a - Fatal - <u>Results in Death</u>), Haemorrhagic cerebral infarction (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
178	EU-EC- 10010254310		2021-10- 07	Healthcare Professional	Non EEA	Not Specified	Female	Thrombosis (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
179	elick or scan EU-EC- 10010254301		2021-10- 07	Non Healthcare Professional	Non EEA	Not Specified		Acute respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
180	elick or scan EU-EC- 10010253817		2021-10- 07	Non Healthcare Professional	Non EEA	18-64 Years	Male	Bone pain (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cait disturbance (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
181	elick or scan EU-EC- 10010253812		2021-10- 07	Healthcare Professional		65-85 Years	Male	Suspected COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
182	click or scan EU-EC- 10010253694		2021-10- 07	Non Healthcare Professional	Non EEA	Not Specified	Male	Cognitive disorder (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Mental impairment (n/a - Fatal - Results in Death), Other Medically Important Condition), Weight decreased (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
183	EU-EC- 10010253678	IN COMPANY (ASS.)	2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Blood test (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disabling), Coronary artery disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disabling), Heachche (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disabling), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disabling), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disabling), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Uniform Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -) Brain stem haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardo-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardo-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition) Sakken death (n/a - Fatal - Results in Death) Myocardial infarction (n/a - Fatal - Results in Death), Nasopharyngitis (n/a - Fatal - Results in Death), Ventricular extrasystoles (n/a - Fatal - Results in Death) Cerebrovascular accident (2d - Fatal - Results in Death) Cerebrovascular accident (2d - Fatal - Results in Death) Altered state of consciousness (n/a - Fatal - Results in Death) Altered state of consciousness (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
184	EU-EC- 10010253650		07	Healthcare Professional	Non EEA	65-85 Years	Male	Cough (n/a - Unknown -), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
185	EU-EC- 10010253609		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Brain stem haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebral ventricular rupture (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
186	EU-EC- 10010252796		2021-10- 07	Healthcare Professional	EEA	18-64 Years	Female	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
187	EU-EC- 10010252567		07	Healthcare Professional	EEA	65-85 Years	Male	Myocardial infarction (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular])
188	EU-EC- 10010252548		2021-10- 07	Healthcare Professional	EEA	65-85 Years	Male	Bile duct cancer (n/a - Fatal - Results in Death), Nasopharyngitis (n/a - Fatal - Results in Death), Ventricular extrasystoles (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - land - [n/a - n/a - n/a])
189	EU-EC- 10010252533			Healthcare Professional	EEA	More than 85 Years	Female	Cerebrovascular accident (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
190	EU-EC- 10010252530			Healthcare Professional	EEA	65-85 Years	Male	Death (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
191	EU-EC- 10010252528	国际政治(44.6)		Healthcare Professional	EEA	More than 85 Years	Female	Altered state of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
192	10010252506		07	Healthcare Professional	EEA	65-85 Years	Male	Acute respiratory failure (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [92d - 3 {DF} - Intramuscular])
193	EU-EC- 10010252444	回 古州回 西原 5 5 回 5 5 4	2021-10- 07	Healthcare Professional	EEA	65-85 Years	Male	Haemorrhagic stroke (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])

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		EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
	194	EU-EC- 10010252431		2021-10- 07	Healthcare Professional	EEA	More than 85 Years	Female	COVID-19 pneumonia (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [20d - 2{DF} - Intramuscular])
:	1 95	EU-EC- 10010252389		2021-10- 07	Healthcare Professional	EEA	More than 85 Years	Female	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular])
-	. 96	click or scan EU-EC- 10010252326		2021-10- 07	Healthcare Professional	Non EEA	Not Specified	Male	Cerebrovascular accident (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	immunisation - Not applicable - [20d - 2{DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1{DF} - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
	97	<u>click or scan</u> EU-EC- 10010252239		2021-10- 07	Healthcare Professional	EEA	Not Specified	Female	Foetal death (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Foetal hypokinesia (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])
	198	EU-EC-10010252234		2021-10- 07	Healthcare Professional	EEA	65-85 Years	Female	Cough (n/a - Fatal - Results in Death), Dizziness (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Sudden cardiac death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
	199	EU-EC- 10010252215		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Male	Aspiration (n/a - Fatal - Results in Death, Other Medically Important Condition), Cyanosis (n/a - Unknown -), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Marasmus (n/a - Fatal - Results in Death), Obstructive airways disorder (n/a - Unknown -), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
2	200	EU-EC- 10010252194		2021-10- 07	Healthcare Professional	EEA	65-85 Years	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Drug ineffective (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
2	201	EU-EC- 10010252112		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Female	Cardiac failure (n/a - Fatal - Results in Death), Disease progression (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Myocardial fibrosis (n/a - Fatal - Results in Death), Myocardial ischaemia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
:	202	click or scan EU-EC- 10010252023		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Haemoptysis (n/a - Fatal - <u>Results in Death,</u> Caused/Prolonged Hospitalisation), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown])

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#	EU Local Number	ICSR Form	Gateway Receipt Date	Source Qualification	Country	Age C	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
203	elick or scan EU-EC- 10010252000		2021-10- 07	Healthcare Professional	IINON EEA I	65-85 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
204	EU-EC- 10010251935		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Female	Acute myocardial infarction (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Chest pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
205	EU-EC- 10010251933		07	Healthcare Professional	Non EEA	More than 85 Years	Female	Immunisation (n/a - Unknown -), Off label use (n/a - Unknown -), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
206	EU-EC- 10010251852		2021-10- 07	Non Healthcare Professional	Non EEA	Not Specified	Male	Death (n/a - Fatal - <u>Results in Death</u>), Illness (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
207	EU-EC- 10010251834		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Completed suicide (n/a - Fatal - Results in Death), Schizophrenia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
208	EU-EC- 10010251624			Healthcare Professional	EEA	More than 85 Years	Female	COVID-19 (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])
209	EU-EC- 10010251543		2021-10- 07	Healthcare Professional	EEA	More than 85 Years	Male	COVID-19 (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S-Immunisation - Not applicable - [n/a3mL - Intramuscular])
210	EU-EC- 10010251526		07	Healthcare Professional	Non EEA	65-85 Years	Male	Alcohol poisoning (n/a - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (n/a - Fatal - Results in Death), Hepatic failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
211	EU-EC- 10010251212		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
212	EU-EC- 10010251167		2021-10- 07	Non Healthcare Professional	Non EEA	18-64 Years	Male	Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
213	EU-EC- 10010251101		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Pleural effusion (n/a - Fatal - <u>Results in Death</u>), Pneumonia (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>), Respiratory failure (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])

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		Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
2	14			2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Female	Dyskinesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
2	15	EU-EC- 0010251051		2021-10- 07	Non Healthcare Professional	Non EEA	18-64 Years		Acute myocardial infarction (1d - Fatal - Results in Death, Other Medically Important Condition), Altered state of consciousness (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown])
2	16	EU-EC- 0010251007		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Back pain (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Life Threatening), Cardiac failure (n/a - Fatal - Results in Death), Haematuria (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Life Threatening), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
2	17	EU-EC- 0010250744			Healthcare Professional	Non EEA	65-85 Years	Male	Acute myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Fatal - Results in Death, Other Medically Important Condition), Hyperkalaemia (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Myocardial rupture (n/a - Fatal - Results in Death), Other Medically Important Condition), Pericardial effusion (n/a - Fatal - Results in Death), Other Medically Important Condition), Sertor (n/a - Fatal - Results in Death), Ventricular fibrillation (n/a - Fatal - Results in Death), Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
2	18	EU-EC- 0010250725		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Cardiac arrest (n/a - Fatal - <u>Results in Death</u>), Cardiac failure acute (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
2	19	click or scan		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Other Medically Important Condition), Productive cough (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
2	20	click or scan EU-EC- 0010250702		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Arrhythmia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	immunisation - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a - Intramuscular])
2	21	EU-EC- 0010250685		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Male	Pancytopenia (n/a - Fatal - Results in Death, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
2	22	EU-EC- 0010250653		2021-10- 07	Healthcare Professional	EEA	65-85 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])

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#	Number	ICSK FORM	Gateway	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Age	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
223	EU-EC- 10010249977		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Adverse event following immunisation (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular])
224	10010249665			Healthcare Professional	EEA	65-85 Years	Male	Asthenia (n/a - Fatal - Results in Death), Lividity (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death), Vaccination site discolouration (n/a - Fatal - Results in Death), Vaccination site reaction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])
225	click or scan EU-EC- 10010249517		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years		Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
226	click or scan			Healthcare Professional	Non EEA	65-85 Years	Male	Arteriosclerosis coronary artery (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
227	click or scan EU-EC- 10010249501		2021-10- 07	Healthcare Professional		65-85 Years	Male	Pneumonia (9d - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Pulmonary embolism (9d - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])
228	click or scan EU-EC- 10010249414		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Cardiac disorder (71d - Fatal - Results in Death), Escherichia infection (71d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S-COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
229	click or scan		2021-10- 07	Non Healthcare Professional		65-85 Years	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - 1 {DF} - n/a])
230	EU-EC- 10010248879		2021-10- 07	Non Healthcare Professional	EEA	18-64 Years	Male	Cough (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - <u>Results in Death</u>)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a])
231	EU-EC- 10010248871		2021-10- 07	Non Healthcare Professional		65-85 Years	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])

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#		EU Local Number		EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
23	32	<u>click or scan</u> EU-EC- 10010248649		2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	Not Specified	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nephrostomy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nosocomial infection (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Papilloma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ureteric obstruction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a])
23	33	EU-EC- 10010248234		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Deep vein thrombosis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematuria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemorrhage subcutaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic diathesis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Fatal - Results in Death), Mouth haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - lIntramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
23	34	EU-EC- 10010248217		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
23	35	click or scan EU-EC- 10010248212		2021-10- 07	Non Healthcare Professional	Non EEA	65-85 Years		Drug ineffective (n/a - Fatal - Results in Death.) Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Immunisation (n/a - Unknown -), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown -), Suspected COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
23	36	EU-EC-10010248208		2021-10- 07	Non Healthcare Professional	Non EEA	65-85 Years	Male	Cardiomegaly (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
23	37	click or scan EU-EC- 10010248195		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Acute kidney injury (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
23	88	EU-EC-10010248018		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years		Cough (n/a - Fatal - <u>Results in Death</u>), Nasopharyngitis (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
23	39	click or scan EU-EC- 10010248015		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown -), Ileus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Insomnia (n/a - Unknown -), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
24	10	click or scan EU-EC- 10010247964		2021-10- 07	Healthcare Professional	EEA	More than 85 Years		Dyspnoea (9d - Fatal - <u>Results in Death</u>), Malaise (9d - Fatal - <u>Results in Death</u>), Somnolence (9d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])

#	EU Local Number	ICSR Form		Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
241	EU-EC- 10010247914			Healthcare Professional	EEA	65-85 Years	Female	Cardiac failure (10d - Fatal - Results in Death), Dyspnoea exertional (10d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])
242	EU-EC- 10010247900			Healthcare Professional	EEA	More than 85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
243	EU-EC- 10010247894		2021-10- 07	Healthcare Professional	EEA	65-85 Years	Female	Death (0d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
244	click or scan			Healthcare Professional	EEA	18-64 Years	Male	Acute abdomen (46d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Anastomotic complication (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Blood product transfusion dependent (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal ischaemia (46d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Shock haemorrhagic (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a])
245	click or scan EU-EC- 10010247567		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
246	click or scan		2021-10- 07	Non Healthcare Professional	Non EEA	18-64 Years	Male	Chest discomfort (7d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
247	click or scan EU-EC- 10010247423		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Female	Brain death (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain hemiation (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Corebral venous sinus thrombosis (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Fatal - Results in Death), Fibrin D dimer increase (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Fibrin D dimer increased (n/a - Fatal - Results in Death), Under Medically Important Condition), Hemiparesis (n/a - Fatal - Results in Death), Hydrocephalus (n/a - Fatal - Results in Death), Under Medically Important Condition), Hemiparesis (n/a - Fatal - Results in Death), Hydrocephalus (n/a - Fatal - Results in Death), Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nususca (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachno	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 inmunisation - Unknown - [1d - n/a - Intramuscular])
248	<u>click or scan</u> EU-EC- 10010247361		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Arrhythmia (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Fatal - Results in Death), Depressed level of consciousness (3h - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
249	click or scan		2021 10	Non Healthcare Professional	Non EEA	65-85 Years	Male	Furuncle (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
250	click or scan		2021 10	Non Healthcare Professional	EEA	18-64 Years	Male	Asthenia (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Skin discolouration (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- Immunisation - Not applicable - [n/a5mL - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Source	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
251	click or scan EU-EC- 10010247090		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Female	Aortic valve sclerosis (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchial haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic steatosis (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung induration (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mucosal haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Re	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1mL - Intramuscular])
252	click or scan EU-EC- 10010247023	□.301 ·Oit. →	2021-10- 07	Healthcare Professional	EEA	18-64 Years	Female	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])
253	click or scan EU-EC- 10010246991		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Female	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Alanine aminotransferase increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Coldsweat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug intolerance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastroenteritis viral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrointestinal oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Holiance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Me	

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
254	EU-EC-		2021-10- 07	Healthcare Professional	EEA	More than 85 Years		Body temperature increased (1d - Fatal - <u>Results in Death</u>), Oxygen saturation decreased (1d - Fatal - <u>Results in Death</u>), Pneumonia (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
255	EU-EC- 10010246809		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years		Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
256	EU-EC- 10010246803		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years		Aortic dissection (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - Results in Death, Other Medically Important Condition), Shock (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
257	click or scan EU-EC- 10010246755		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral mass effect (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nausea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Superior sagittal sinus thrombosis (3d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	(CHADOX1 NCOV-19)] (S - COVID-19 immunisation Not applicable - [1d - n/a - Intramuscular])
258	EU-EC- 10010246744		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Male	COVID-19 (3d - Fatal - Results in Death , Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
259	EU-EC- 10010246568		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years		Acute myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial flutter (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
260	elick or scan EU-EC- 10010246470		2021-10- 07	Healthcare Professional	Non EEA	Not Specified		Cardiac death (n/a - Fatal - Results in Death), Cardiac failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
261	EU-EC- 10010246355		2021-10- 07	Healthcare Professional	EEA	More than 85 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])
262	click or scan EU-EC- 10010246268		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (5d - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
263	EU-EC- 10010245975		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Loss of consciousness (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
264	EU-EC- 10010245974		2021-10- 07	Healthcare Professional	Non EEA	18-64 Years		Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation), Stertor (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
265	click or scan EU-EC- 10010245966		2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Dysstasia (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition)	immunisation - Not applicable - [Id - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
266	EU-EC- 10010245957			Healthcare Professional	Non EEA	More than 85 Years	Female	Fall (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
267	EU-EC- 10010245949		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Interstitial lung disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
268	<u>click or scan</u> EU-EC- 10010245948		2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Female	Acute myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
269	EU-EC- 10010245838		2021-10- 07	Non Healthcare Professional	Non EEA	18-64 Years	Female	Cardiac failure (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S-n/a-Drug withdrawn- [n/a-n/a-Intramuscular])
270	EU-EC- 10010245693		2021-10- 07	Non Healthcare Professional	Non EEA	65-85 Years	Female	Aphasia (n/a - Fatal - Results in Death), Eating disorder (n/a - Unknown -), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown -)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
271	EU-EC- 10010245555		2021-10- 07	Non Healthcare Professional	EEA	18-64 Years		Acute kidney injury (66d - Fatal - Results in Death), Alveolitis (66d - Fatal - Results in Death), Arthralgia (66d - Fatal - Results in Death), Cardiac arrest (66d - Fatal - Results in Death), Conjunctival hyperaemia (66d - Fatal - Results in Death), Joint swelling (66d - Fatal - Results in Death), Multiple organ dysfunction syndrome (66d - Fatal - Results in Death), Pain in extremity (66d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - n/a - [n/a5mL - Intramuscular])
272	EU-EC- 10010245369	TELEVICION CANADAM CAN	2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	Male	Cardiac arrest (0d - Fatal - <u>Results in Death</u>), Death (0d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
273	click or scan EU-EC- 10010245097	1 C C C C C C C C C C C C C C C C C C C	2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	Male	Cardiomegaly (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Ischaemia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])

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#	EU Local Number	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
274	EU-EC- 10010245014	2021-10- 07	Non Healthcare Professional	EEA	More than 85 Years	Female	Injection site reaction (n/a - Fatal - <u>Results in Death</u>), Pulmonary embolism (n/a - Fatal - <u>Results in Death</u>), SARS-CoV-2 test positive (n/a - Fatal - <u>Results in Death</u>), Thrombosis (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
275	click or scan EU-EC- 10010243318	2021-10- 07	Healthcare Professional	Non EEA	18-64 Years		Death (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Illness (n/a - Unknown -), Influenza like illness (n/a - Unknown -), Mobility decreased (n/a - Unknown -)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
276	click or scan EU-EC- 10010243245	2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	remale	Asthma (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Respiratory disorder (n/a - Unknown -), Sputum retention (n/a - Unknown -), Wheezing (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
277	EU-EC- 10010243237	2021-10- 07	Non Healthcare Professional	Non EEA	65-85 Years		COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - n/a])
278	EU-EC- 10010243178	2021-10- 07	Healthcare Professional	Non EEA	65-85 Years	iviaie	Cerebral infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
279	EU-EC- 10010243066	2021-10- 07	Healthcare Professional	Non EEA	More than 85 Years	Male	Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
280	EU-EC- 10010243059	2021-10- 07	Healthcare Professional	Non EEA	18-64 Years	Male	Circulatory collapse (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Feeling abnormal (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
281	click or scan EU-EC- 10010243036	2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	Male	Acute myocardial infarction (0d - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA] (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
282	click or scan EU-EC- 10010243035	2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	Male	Cerebral haemorrhage (n/a - Fatal - <u>Results in Death</u>), Leukaemia (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
283	click or scan EU-EC- 10010243012	2021-10- 07	Non Healthcare Professional	EEA	More than 85 Years	Female	Arthralgia (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Neck pain (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 - Not applicable - [n/a - 1 {DF} - Intramuscular])

#	EU Local Number		EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
284	<u>click or scan</u> EU-EC- 10010243010		2021-10- 07	Non Healthcare Professional	EEA	18-64 Years	Male	Acute coronary syndrome (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
285	<u>click or scan</u> EU-EC- 10010242999	国際教権を移る数3	2021-10- 07	Non Healthcare Professional	EEA	18-64 Years	Male	Infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
286	EU-EC- 10010242985		07	Healthcare Professional	EEA	65-85 Years	Female	Aortic stenosis (1d - Fatal - <u>Results in Death</u>), Death (1d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])
287	EU-EC- 10010242945		2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	Female	Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
288	EU-EC- 10010242762		2021-10- 07	Non Healthcare Professional	EEA	65-85 Years	Male	Sudden death (0d - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
289	EU-EC- 10010242695		2021-10- 07	Healthcare Professional	EEA	18-64 Years		Asthenia (0d - Fatal - <u>Results in Death</u>), Headache (0d - Fatal - <u>Results in Death</u>), Sudden death (0d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
290	EU-EC- 10010244461		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
291	click or scan EU-EC- 10010244082		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Abdominal pain (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Arteriosclerosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Coeliac artery stenosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Grimacing (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric arterial occlusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
292	click or scan EU-EC- 10010244027		2021-10- 06	Non Healthcare Professional	Non EEA	18-64 Years	NOT Specified	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Country			Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
293	EU-EC- 10010244018		2021-10- 06	Non Healthcare Professional	Non EEA	18-64 Years	Female	Back pain (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S- Immunisation - Not applicable - [n/a - n/a - Unknown])
294	EU-EC- 10010244016		2021-10- 06	Non Healthcare Professional	EEA	18-64 Years		Suspected COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S] (S - Immunisation - Not applicable - [n/a5mL - Unknown])
295	elick or scan EU-EC- 10010243985		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	Acute respiratory failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
296	EU-EC- 10010243676		2021-10- 06	Non Healthcare Professional	Non EEA			Suspected COVID-19 (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Vaccination failure (n/a - Unknown - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
297	click or scan EU-EC- 10010243658		2021-10- 06	Healthcare Professional		65-85 Years	Male	Balance disorder (n/a - Unknown - <u>Results in Death</u>), Cardiac arrest (n/a - Fatal - <u>Results in Death</u>), Cerebral infarction (n/a - Unknown - <u>Results in Death</u>), Dysarthria (n/a - Unknown - <u>Results in Death</u>), Cait disturbance (n/a - Unknown - <u>Results in Death</u>), Motor dysfunction (n/a - Unknown - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Intramuscular])
298	EU-EC- 10010243656		2021-10- 06	Healthcare Professional		18-64 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
299	click or scan EU-EC- 10010243633		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Immune thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myocardial strain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory tract infection (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
300	click or scan EU-EC- 10010243611			Healthcare Professional		18-64 Years	Female	Sudden death (n/a - Fatal - <u>Results in Death</u> , Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular])

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	# 1	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
3	301	EU-EC- 10010243579		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Female	Loss of consciousness (n/a - Not Recovered/Not Resolved - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
	302	click or scan EU-EC- 10010243551			Healthcare Professional	Non EEA	18-64 Years	Female	Brain oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral amyloid angiopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematemesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperatraemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Intestinal dilatation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intracranial tumour haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Thrombosis mesenteric vessel (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis mesenteric vessel (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
	303	click or scan EU-EC- 10010243550		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown -), Intracranial pressure increased (n/a - Unknown - Other Medically Important Condition), Supor (n/a - Unknown - Other Medically Important Condition), Supor (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular])
	304	click or scan EU-EC- 10010242606		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	Cerebrovascular accident (55d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Creutzfeldt-Jakob disease (4d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dizziness (108d - Unknown - Caused/Prolonged Hospitalisation), Insomnia (108d - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
3	305	EU-EC- 10010242445		2021-10- 06	Non Healthcare Professional	Non EEA	18-64 Years		COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
[3	306	EU-EC- 10010242370		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Pulmonary embolism (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
	307	EU-EC- 10010242071			Healthcare Professional	Non EEA	65-85 Years		Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown -), Pyrexia (1d - Recovered/Resolved -), Respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Qualification	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
308	click or scan EU-EC- 10010241884	The Company of the Co	2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	Aphasia (3d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (3d - Fatal - Results in Death. Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drooling (3d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (3d - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (3d - Unknown - Other Medically Important Condition), Myocardial infarction (3d - Fatal - Results in Death. Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (3d - Fatal - Results in Death.)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
309	EU-EC- 10010241862		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Male	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
310	click or scan EU-EC- 10010241835		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Female	Acute respiratory distress syndrome (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), COVID-19 pneumonia (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Dyspnoea (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pryerxia (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
311	EU-EC- 10010241717			Healthcare Professional	Non EEA	More than 85 Years	Female	Acute left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Extra dose administered (n/a - Unknown - Caused/Prolonged Hospitalisation), Stress cardiomyopathy (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR])
312	EU-EC- 10010241501			Healthcare Professional	Non EEA	Not Specified	Male	Discomfort (n/a - Unknown -), Fall (n/a - Unknown -), Fatigue (n/a - Unknown -), Myocarditis (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
313	EU-EC- 10010240983	1 美工程的 1500年 1000年 1		Healthcare Professional	Non EEA	65-85 Years	Female	Cardiogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])

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#		EU Local Number	ICSR Form	EV Gateway Receipt Date	O1:6:4:	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
31		click or scan EU-EC- 10010240779		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Female	Abdominal pain lower (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acidosis (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute kidney injury (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anuria (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cother Medically Important Condition), Back pain (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cather Medically Important Condition), Dialysis (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gastrointestinal inflammation (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gastrointestinal wall thickening (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gastrointestinal wall thickening (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypothermia (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General Prolonged Hospitalisation, Other Medically Important Condition), Hypothermia (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sowresponse to stimuli (
31		EU-EC- 10010240736			Healthcare Professional	Non EEA	18-64 Years	Male	Death (5d - Fatal - Results in Death, Other Medically Important Condition), Malaise (5d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
31	16	elick or scan EU-EC- 10010240501			Healthcare Professional	Non EEA	More than 85 Years	Female	Acute myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
31	17	EU-EC- 10010240382		2021-10- 06	Non Healthcare Professional	Non EEA	Not Specified	Not Specified	Suspected COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
31	18	EU-EC-10010240378		2021-10- 06	Non Healthcare Professional	Non EEA	Not Specified		Suspected COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
31	19	click or scan			Healthcare Professional	Non EEA	65-85 Years	Female	Acute kidney injury (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chronic kidney disease (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rhinorrhoea (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
32	20	EU-EC- 10010239962		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Female	Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

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EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC- 10010239652		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Female		COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
<u>click or scan</u> EU-EC- 10010239636		2021-10- 06		Non EEA	65-85 Years	Male	Dyspnoea (43d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
EU-EC- 10010239574		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Male		SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
click or scan EU-EC- 10010239509		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), RITUXIMAB [RITUXIMAB] (S - Multifocal motor neuropathy - n/a - [1d - 500mg - n/a]), [HUMAN NORMAL IMMUNOGLOBULIN, HUMAN NORMAL IMMUNOGLOBULIN (IV), IMMUNOGLOBULIN G] (S - Multifocal motor neuropathy - n/a - [1d - 60g - n/a])
<u>click or scan</u> EU-EC- 10010239508		2021-10- 06		EEA	65-85 Years	iviaie	COVID-19 (14d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (14d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (14d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (14d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
EU-EC- 10010239242		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Female		ا آگا
EU-EC- 10010239172		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Female	COVID-19 (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death)	VAXZEVRIA [COMD-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular])
<u>click or scan</u> EU-EC- 10010239171		2021-10- 06		EEA	More than 85 Years	Female	COVID-19 (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular])
EU-EC- 10010239167		2021-10- 06	Non Healthcare Professional	EEA	65-85 Years	Male		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
EU-EC- 10010239137		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Female		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular])
	EU Local Number click or scan EU-EC- 10010239652 click or scan EU-EC- 10010239574 click or scan EU-EC- 10010239579 click or scan EU-EC- 10010239509 click or scan EU-EC- 10010239508 click or scan EU-EC- 10010239171 click or scan EU-EC- 10010239171 click or scan EU-EC- 10010239171 click or scan	Click or scan	Click or scan	EU Local Number ICSR Form Gateway Receipt Date Click or scan EU-EC-10010239652 Click or scan EU-EC-10010239574 Click or scan EU-EC-10010239574 Click or scan EU-EC-10010239509 Click or scan EU-EC-10010239172 Click or scan EU-EC-10010239172 Click or scan EU-EC-10010239171 Click or scan EU-EC-10010239177	Country Coun	EU Local Number LCSR Form Receipt Out Primary Source Country for Regulatory Purposes Click or scan EU-EC-10010239652 Click or scan EU-EC-10010239574 Click or sc	Primary Source Country for Gregations Primary Source Qualification Primary Source Ground Professional Professional	Plant Continue Principle Plant Continue Plant Plant Plant Continue Plant Continue Plant Continue Plant Continue Plant Continue Plant Plant

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	O 11.01 /1	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
331	EU-EC- 10010239134		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Female	Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
332	EU-EC- 10010239119		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Female	Vaccination failure (29d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular])
333	EU-EC- 10010239092			Healthcare Professional	EEA	65-85 Years	Male	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])
334	click or scan			Healthcare Professional	EEA	65-85 Years	Male	COVID-19 pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [29d - 2{DF} - Intramuscular])
335				Healthcare Professional	EEA	65-85 Years	Female	Peripheral ischaemia (n/a - Fatal - <u>Results in Death</u>), Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
336	EU-EC- 10010238567			Healthcare Professional	Non EEA	18-64 Years	Female	Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Melaena (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
337	EU-EC- 10010238058			Healthcare Professional	Non EEA	65-85 Years	Female	Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
338	EU-EC- 10010237992	三	06	Non Healthcare Professional	Non EEA	Not Specified	Male	COVID-19 (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
339	EU-EC- 10010237983		2021-10- 06	Non Healthcare Professional	EEA	18-64 Years	Male	Arthralgia (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Hyperhidrosis (n/a - Fatal - Results in Death), Palpitations (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
340	EU-EC- 10010237872			Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

#	EU Local Number	ICSR Form	Gateway	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	
341	elick or scan EU-EC- 10010237756	INTORNERS (453)	2021-10- 06	Healthcare Professional	EEA	65-85 Years	Male	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cystitis noninfective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - n/a])	10 2021
342	EU-EC- 10010237643		06	Healthcare Professional	Non EEA	18-64 Years	Male	Abdominal pain (n/a - Fatal - <u>Results in Death</u>), Arthralgia (n/a - Fatal - <u>Results in Death</u>), Diarrhoea (n/a - Fatal - <u>Results in Death</u>), Headache (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	te an Data: OC
343	EU-EC- 10010237512	E1128 MORN 450	2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	Respiratory distress (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])	name admanar
344	<u>click or scan</u> EU-EC- 10010237454		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Amyotrophic lateral sclerosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])	a. EndraViailanca
345	EU-EC- 10010237401		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])	Data Cource: E
346	EU-EC- 10010237276		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular])	٦,
347	EU-EC- 10010237145			Non Healthcare Professional	EEA	Not Specified	Male	Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ton Analysea Dro
348		同当を始める30年		Healthcare Professional	Non EEA	65-85 Years		Aphasia (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Cait inability (n/a - Unknown - Other Medically Important Condition), Terminal state (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])	http://t.mo/Do
349	EU-EC- 10010236692		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Female	Epilepsy (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Hyperpyrexia (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Created hy
350	EU-EC- 10010236689		2021-10- 06	Professional	EEA	More than 85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	
351	elick or scan EU-EC- 10010236621		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	COVID-19 (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])	

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
352	<u>click or scan</u> EU-EC- 10010236497		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Male	Asthenia (5d - Fatal - Results in Death), Atrial fibrillation (3d - Fatal - Results in Death), Cholestasis (1d - Fatal - Results in Death), Cyanosis (3d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Delirium (2d - Fatal - Results in Death), Dyspnoea at rest (5d - Fatal - Results in Death), Hypotension (3d - Fatal - Results in Death), Lactic acidosis (2d - Fatal - Results in Death), Myalgia (5d - Fatal - Results in Death), Oliguria (1d - Fatal - Results in Death), Oxygen saturation decreased (3d - Fatal - Results in Death), Renal failure (1d - Fatal - Results in Death), Respiratory distress (3d - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
353	EU-EC- 10010236496	国际内域(4.6.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4	2021-10- 06	Healthcare Professional	EEA	18-64 Years	Female	Death (0d - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
354	EU-EC- 10010236346		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Female	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Haematemesis (n/a - Fatal - Results in Death), Headache (n/a - Unknown - Other Medically Important Condition), Melaena (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Portal vein thrombosis (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	RIVAROXABAN [RIVAROXABAN] (I - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular])
355	click or scan EU-EC- 10010236311		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Aphasia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous thrombosis (3d - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma scale abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Superior sagittal sinus thrombosis (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) RIVAROXABAN [RIVAROXABAN] (I - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
356	EU-EC- 10010236305		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Male	COVID-19 (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
357	EU-EC- 10010236276		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	Asthenia (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Atrial fibrillation (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Dyspnoea (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Syncopo (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
358	EU-EC- 10010236244		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Male	Asthenia (17d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (17d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
359	click or scan EU-EC- 10010236124		2021-10- 06	Healthcare Professional	EEA	18-64 Years	Female	Chills (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Sudden death (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])

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;		IU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
3	60			2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Cardiovascular disorder (0d - Fatal - <u>Results in Death</u>), Headache (1d - Fatal - <u>Results in Death</u>), Pyrexia (2d - Fatal - <u>Results in Death</u>)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
3	61	EU-EC- 0010235991		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (1d - Fatal - <u>Results in Death</u>), Cardiac arrest (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
3	62	EU-EC- 0010235952		2021-10- 06	Healthcare Professional	EEA	18-64 Years	Male	COVID-19 (24d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (24d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOXI-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S- Immunisation - Not applicable - [n/a5mL - Intramuscular])
3	63	click or scan EU-EC- 0010235926		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death), Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Extensor plantar response (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Mydriasis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Photophobia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Somospeech (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Somospech (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - 1 {DF} - Intramuscular])
3	64	EU-EC- 0010235881		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (1d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
3	65	EU-EC- 0010235620		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
3	66	click or scan EU-EC- 0010235571		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Aphasia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous thrombosis (3d - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Superior sagittal sinus thrombosis (2d - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Disabling), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Disabling)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	Gateway	Qualification	for	Age	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
367	click or scan EU-EC- 10010235484		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Female	Acute chest syndrome (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death), Cardiac failure acute (n/a - Fatal - Results in Death), Chest pain (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Crepitations (n/a - Fatal - Results in Death), Deafhess neurosensory (n/a - Fatal - Results in Death), Deep vein thrombosis (n/a - Fatal - Results in Death), Disseminated intravascular coagulation (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hyperhidrosis (n/a - Fatal - Results in Death), Hypotalaemia (n/a - Fatal - Results in Death), Metabolic acidosis (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Pulmonary hypertension (n/a - Fatal - Results in Death), Sickle cell disease (n/a - Fatal - Results in Death), Sinus tachycardia (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular])
368	<u>click or scan</u> EU-EC- 10010235474		2021-10- 06	Non Healthcare Professional		65-85 Years	Male	COVID-19 (12d - Fatal - <u>Results in Death</u> , Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
369	click or scan EU-EC- 10010235408		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years		Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Gastric haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic cirrhosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
370	EU-EC- 10010235394			Healthcare Professional	EEA	Not Specified	Female	Acute respiratory distress syndrome (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
371	EU-EC- 10010235166		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	Acute myocardial infarction (0d - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Depressed level of consciousness (0d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
372	click or scan EU-EC- 10010235080			Healthcare Professional	Non EEA	More than 85 Years	Male	Asthenia (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown -), Incontinence (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung opacity (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Tachypnoea (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urine abnormality (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urine abnormality (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	
373	click or scan EU-EC- 10010235014		2021-10- 06	Healthcare Professional		65-85 Years		Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung consolidation (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung opacity (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	
374	EU-EC- 10010234986		2021-10- 06	Healthcare Professional	EEA	More than 85 Years		Coma (1d - Fatal - Results in Death), Epilepsy (n/a - Unknown - Other Medically Important Condition), Haemorrhagic cerebral infarction (1d - Fatal - Results in Death), Hypertensive crisis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])

#	EU Local Number	ICSR Form		Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
375	EU-EC- 10010234954	同じを始める。		Healthcare Professional	Non EEA	65-85 Years	Male	Acute kidney injury (7d - Fatal - Results in Death, Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (7d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (7d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
376	EU-EC- 10010234909		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years		COVID-19 (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiopulmonary failure (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
377	EU-EC- 10010234883		2021-10- 06	Healthcare Professional	EEA	65-85 Years	Male	Balance disorder (66d - Fatal - <u>Results in Death</u>), Cognitive disorder (66d - Fatal - <u>Results in Death</u>), Dysarthria (66d - Fatal - <u>Results in Death</u>), Nervous system disorder (66d - Fatal - <u>Results in Death</u>), Skin disorder (66d - Fatal - <u>Results in Death</u>)	applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
378	EU-EC- 10010234862	同説を概念者を使わ	2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S-COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
379	EU-EC- 10010234854	[12] (12) (42) (42) (42)	06	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA
380	EU-EC- 10010234722		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	
381	elick or scan EU-EC- 10010234458		2021-10- 06	Non Healthcare Professional	EEA	65-85 Years	Male	Cerebrovascular accident (n/a - Fatal - <u>Results in Death</u>)	(CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
382	EU-EC- 10010234387			Healthcare Professional	Non EEA	18-64 Years	Female	Atrioventricular block (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
383	EU-EC- 10010234362		2021-10- 06	Non Healthcare Professional	Non EEA	18-64 Years	Male	Seizure (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
384	EU-EC- 10010234334	国(1994年2月5日)	06	Healthcare Professional	Non EEA	65-85 Years	Male	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Jaundice (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
385	EU-EC- 10010234227		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years		Aortic valve replacement (n/a - Fatal - Results in Death), Cardiac procedure complication (n/a - Fatal - Results in Death), Haemorrhage (n/a - Fatal - Results in Death), Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
386	click or scan EU-EC- 10010234048		2021-10- 06	Non Healthcare Professional	EEA	More than 85 Years	Male	Cerebrovascular accident (10d - Fatal - Results in Death, Other Medically Important Condition), Septic shock (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
387	EU-EC- 10010233952		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Male	COVID-19 (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urinary tract infection bacterial (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation n/a - [n/a - 3 {DF} - n/a])
388	EU-EC- 10010233798		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
389	EU-EC- 10010233625		06	Healthcare Professional	Non EEA	65-85 Years	Male	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Inflammatory bowel disease (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
390	EU-EC- 10010233389		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Female	Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])
391	click or scan			Healthcare Professional	Non EEA	65-85 Years	Male	Acute respiratory failure (34d - Fatal - Results in Death, Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (34d - Fatal - Results in Death, Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (34d - Fatal - Results in Death, Life Threatening Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Life Threatening Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (34d - Fatal - Results in Death, Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (34d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
392	EU-EC- 10010233369		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
393	EU-EC- 10010233269		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Female	COVID-19 (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Exposure to contaminated air (6d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
394	click or scan EU-EC- 10010233192		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	Acute respiratory failure (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoglycaemic coma (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
395	EU-EC- 10010233124		06	Healthcare Professional	Non EEA	18-64 Years	Female	COVID-19 (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoca (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoca (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Haemodialysis (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypervolaemia (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypervolaemia (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])

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396	click or scan EU-EC- 10010233123	2021-10- 06	- Healthcare Professional	Non EEA	18-64 Years	Male	Ascites (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown -), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cardiogenic shock (1d - Fatal - Results in Death, Other Medically Important Condition), Cardiomegaly (n/a - Unknown -), Congestive hepatopathy (n/a - Unknown - Other Medically Important Condition), Hepatic failure (n/a - Unknown - Other Medically Important Condition), Hepatomegaly (n/a - Unknown -), Hyperventilation (n/a - Unknown -), Inflammation (n/a - Unknown -), Metabolic acidosis (n/a - Unknown -), Myocarditis (1d - Fatal - Results in Death, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
397	EU-EC- 10010233122	2021-10- 06	· Healthcare Professional	Non EEA	More than 85 Years	Female	Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (1d - Fatal - Results in Death), Extra dose administered (1d - Fatal - Results in Death), Fatigue (1d - Fatal - Results in Death), Feeling abnormal (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death), Pulmonary embolism (1d - Fatal - Results in Death), Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
398	EU-EC- 10010233033	2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years		Asthenia (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
399	EU-EC- 10010233031	2021-10- 06	- Healthcare Professional	EEA	18-64 Years	Male	Sudden cardiac death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])
400	click or scan	2021-10- 06	- Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (14d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
401	EU-EC- 10010233014	2021-10- 06	- Healthcare Professional	Non EEA	More than 85 Years	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Life Threatening), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
402	click or scan EU-EC- 10010232967	2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cellulitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown -), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory symptom (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
403	EU-EC- 10010232925	06	Healthcare Professional	Non EEA	65-85 Years	Male	Myocardial infarction (2d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number		EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
404	click or scan EU-EC- 10010232889		06	Healthcare Professional	Non EEA	65-85 Years		COVID-19 (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest discomfort (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
405	elick or scan EU-EC- 10010232787	THE PARKETS AND AND ADDRESS AN	2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	Acute respiratory failure (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lethargy (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Poor quality sleep (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
406	elick or scan EU-EC- 10010232782	TELESCOPER SECTION	2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Female	Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), End stage renal disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
407	EU-EC- 10010232776			Healthcare Professional	Non EEA	18-64 Years	Female	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
408	EU-EC- 10010232736		2021-10- 06	Non Healthcare Professional	EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>), Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S- n/a - n/a - [n/a - n/a - Intramuscular])
409	EU-EC- 10010232731	同語為經過數數	2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Female	Movement disorder (1d - Fatal - <u>Results in Death</u>), Pain in extremity (1d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
410	EU-EC- 10010232693	国(39) (42) (42)		Healthcare Professional	Non EEA	18-64 Years	Male	Dizziness (n/a - Unknown -), Dyspnoea (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown -)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
411	EU-EC- 10010232564		2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Female	Dyspnoea (2d - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Nausea (2d - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Vomiting (2d - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
412				Healthcare Professional	Non EEA	65-85 Years	Female	Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation) Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
413	EU-EC- 10010232458	国 数据 数据 数据	2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
414	EU-EC- 10010232410		2021-10- 06	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (1d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date		Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
41	click or scar 5 EU-EC- 1001023229		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	Male	Abdominal pain (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown -), Dyspnoea (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung infiltration (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])
41	6 EU-EC- 1001023228		2021-10- 06	Healthcare Professional	Non EEA	18-64 Years	rremaie	Cerebral venous sinus thrombosis (n/a - Fatal - <u>Results in Death</u>), Immune thrombocytopenia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])
41	7 EU-EC-1001023211	7 8 8 8	2021-10- 06	Healthcare Professional	Non EEA	More than 85 Years	Female	Atrial fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral artery embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
41	8 EU-EC- 1001023125		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Female	Cough (8d - Fatal - <u>Results in Death</u>), Pyrexia (8d - Fatal - <u>Results in Death</u>), Respiratory failure (8d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
41	elick or scar EU-EC- 1001023125		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Female	Cough (8d - Fatal - <u>Results in Death</u>), Pyrexia (8d - Fatal - <u>Results in Death</u>), Respiratory failure (8d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
42	elick or scar EU-EC- 1001023093		2021-10- 06	Non Healthcare Professional	EEA	65-85 Years	Female	Meningitis (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
42	elick or scar EU-EC- 1001023091		2021-10- 06	Non Healthcare Professional	EEA	65-85 Years		Cardiac arrest (n/a - Fatal - Results in Death), Oropharyngeal pain (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death), Tinnitus (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])
42	click or scar 2 EU-EC- 1001023074		2021-10- 06	Healthcare Professional	EEA	More than 85 Years	Male	Oxygen saturation decreased (0d - Fatal - Results in Death), SARS-CoV-2 test positive (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
42	click or scar 3 EU-EC- 1001023019		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Female	Bacterial infection (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Castrointestinal infection (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
424	EU-EC- 10010230173	型。位为 如、由,算 成为,可	2021-10- 05	Non Healthcare Professional	Non EEA	65-85 Years	iviaie	Brain stem stroke (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])
425	click or scan EU-EC- 10010229870		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	Male	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain oedema (n/a - Unknown - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Escherichia infection (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Escherichia sepsis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Renal failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Spor (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Systemic bacterial infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Systemic bacterial infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Systemic bacterial infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/	[RECOMBINANT] JANNSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Dose not changed - [n/a - 1 {DF} - Intramuscular])
426	EU-EC- 10010229791		2021-10- 05	Healthcare Professional	EEA	65-85 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
427	EU-EC- 10010229338		2021-10- 05	Healthcare Professional	EEA	65-85 Years		Fatigue (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hepatotoxicity (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
428	EU-EC- 10010229308		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Male	Myocardial ischaemia (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])
429	click or scan EU-EC- 10010228982		2021-10- 05	Healthcare Professional	EEA	65-85 Years	Male	Aortic embolus (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved-Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Painful respiration (n/a - Recovered/Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovered/Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Dose not changed - [n/a - 1 {DF} - Intramuscular])
430	click or scan EU-EC- 10010228799			Healthcare Professional	Non EEA	18-64 Years	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Headache (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - Intramuscular])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
431	<u>click or scan</u> EU-EC- 10010228740		2021-10- 05	Non Healthcare Professional	EEA	18-64 Years		COVID-19 (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])
432	EU-EC- 10010228315		2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years		Dyspnoea (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
433	EU-EC- 10010228263		2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Male	Drug ineffective (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
434	EU-EC- 10010228143		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (5d - Fatal - Results in Death , Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
435	EU-EC- 10010228083		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Male	Chills (n/a - Fatal - <u>Results in Death</u>), Death (n/a - Fatal - <u>Results in Death</u>), Fatigue (n/a - Fatal - <u>Results in Death</u>), Malaise (n/a - Fatal - <u>Results in Death</u>), Myalgia (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
436	EU-EC- 10010227980		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Abdominal pain (n/a - Unknown -), Abnormal behaviour (n/a - Unknown -), Breath sounds abnormal (n/a - Unknown -), Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pallor (n/a - Unknown -), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Torticollis (n/a - Unknown -)	[RECOMBINANT] JANSEN [COMID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
437	EU-EC- 10010227974		2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Male	Death (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
438	EU-EC- 10010227832		2021-10- 05	Non Healthcare Professional	EEA	65-85 Years	Female	Cerebral haemorrhage (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
439	EU-EC- 10010227795		2021-10- 05	Healthcare Professional	EEA	More than 85 Years	Male	COVID-19 (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])
440	<u>click or scan</u> EU-EC- 10010227690	1 (2) (3) (4) (4)	05	Healthcare Professional	Non EEA	18-64 Years	Female	Altered state of consciousness (n/a - Fatal - Results in Death), Aphasia (n/a - Fatal - Results in Death), Cerebral venous thrombosis (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Monoplegia (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Partial seizures (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular])
441	<u>click or scan</u> EU-EC- 10010227670		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>), Dyspnoea (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
443	click or scan EU-EC- 10010227382		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Male	Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a])
443	10010227381		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Male	Congestive cardiomyopathy (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
44	EU-EC-10010227322		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	Male	Dry mouth (n/a - Unknown -), Palpitations (n/a - Unknown -), Toxic shock syndrome (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
44:	click or scan EU-EC- 10010227240		2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years	Male	Activated partial thromboplastin time shortened (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood albumin decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - Results in Death), Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Disseminated intravascular coagulation (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Inflammation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (17d - Recovered/Resolved - Life Threatening Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Pulmonary artery thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Thrombosis (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
440	EU-EC- 10010227239		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Chest discomfort (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Recovering/Resolving -), Ventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
44'	click or scan	01420	2021-10- 05	Non Healthcare Professional	EEA	18-64 Years	Male	Arthralgia (n/a - Not Recovered/Not Resolved -), Body temperature increased (n/a - Not Recovered/Not Resolved -), Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Recovered/Resolved -), Condition aggravated (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Faligue (n/a - Not Recovered/Not Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Myalgia (n/a - Not Recovered/Not Resolved -), Myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved -), Pneumonia (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
44	EU-EC-		2021-10- 05	Healthcare Professional	EEA	More than 85 Years	Female	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

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#	EU Local Number		EV Gateway Receipt Date	Primary Source	Country	Age	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
449	elick or scan EU-EC- 10010226901		05	Healthcare Professional	EEA	65-85 Years	Male	Sudden cardiac death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
450	elick or scan EU-EC- 10010226871		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Female	Acute myocardial infarction (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
451	EU-EC- 10010226579		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Female	Cellulitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dermatitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown -), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Septic rash (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Swelling (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
452	click or scan EU-EC- 10010226566		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	Female	Aortic dissection (n/a - Fatal - <u>Results in Death</u>), Cardiac perforation (n/a - Fatal - <u>Results in Death</u>), Cardio-respiratory arrest (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
453	<u>click or scan</u> EU-EC- 10010226554		2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
454	EU-EC- 10010226525		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Female	Aspiration (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
455	click or scan EU-EC- 10010225675		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	Female	Acidosis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (32d - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Unknown - Life Threatening, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Life Threatening, Other Medically Important Condition), Resuscitation (n/a - Unknown - Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
456	<u>click or scan</u> EU-EC- 10010225171		2021-10- 05	Healthcare Professional	EEA	65-85 Years	Female	Cardiac failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [182d - 1{DF} - Intramuscular])
457	click or scan EU-EC- 10010225147		2021-10- 05	Healthcare Professional		More than 85 Years	Female	Vaccination failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number	ICSR Form	Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
458	EU-EC- 10010225140		2021-10- 05	Healthcare Professional	EEA	65-85 Years	Male	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])
459	click or scan			Non Healthcare Professional	EEA	More than 85 Years	Male	Cardiac failure (n/a - Fatal - Results in Death), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
460	click or scan		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	remaie	Acute disseminated encephalomyelitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
461	EU-EC- 10010224752		05	Healthcare Professional	EEA	18-64 Years		Arthralgia (n/a - Recovering/Resolving -), Chest pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (2d - Recovered/Resolved -), Myocarditis (n/a - Fatal - Results in Death), Ventricular fibrillation (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
462	EU-EC- 10010224697		2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years	Male	Confusional state (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
463	EU-EC- 10010224646		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Female	Acute respiratory failure (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (20d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (20d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
464	elick or scan EU-EC- 10010224641		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Female	Brain death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Brain herniation (1d - Fatal - Results in Death), Brain oedema (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death), Caused/Prolonged Hospitalisation), Cor pulmonale acute (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
465	EU-EC- 10010224508		2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
466	<u>click or scan</u> EU-EC- 10010224444		2021-10- 05	Healthcare Professional	EEA	Not Specified	Male	Brain injury (n/a - Fatal - Results in Death), Exposure during pregnancy (n/a - Fatal - Results in Death), Neonatal asphyxia (n/a - Fatal - Results in Death), Premature baby (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])
467	EU-EC- 10010224397		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Female	Acute myocardial infarction (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Drowning (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
468	EU-EC- 10010224280	2021-10- 05	Non Healthcare Professional	Non EEA	65-85 Years	Male	Chest discomfort (n/a - Unknown -), Chest pain (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
469	EU-EC- 10010224254	2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Emphysema (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Unknown - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular])
470	<u>click or scan</u> EU-EC- 10010224212		Healthcare Professional	EEA	More than 85 Years	Male	Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Escherichia test positive (n/a - Unknown -), Lethargy (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - Results in Death), Nitrite urine present (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Red blood cells urine positive (n/a - Unknown -), Sepsis (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death), Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
471	<u>click or scan</u> EU-EC- 10010224211	2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Ataxia (n/a - Not Recovered/Not Resolved -), Cerebral arteriosclerosis (n/a - Unknown -), Cerebral infarction (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation), Dyslalia (n/a - Not Recovered/Not Resolved -), Dysphagia (n/a - Not Recovered/Not Resolved -), Cait disturbance (n/a - Not Recovered/Not Resolved -), Irregular breathing (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death), Respiratory disorder (n/a - Fatal - Results in Death), Thrombotic cerebral infarction (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
472	10010224210		Healthcare Professional	Non EEA	18-64 Years		Acute myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - Results in Death), Coronary artery stenosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Pulmonary congestion (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
473	EU-EC- 10010224202	2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years		Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
474	EU-EC- 10010224193	2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years	Male	Platelet count decreased (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
475	EU-EC- 10010224192	2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Male	Drug ineffective (n/a - Fatal - Results in Death), Suspected COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
476	EU-EC- 10010224182	2021-10- 05	Healthcare Professional	Non EEA	18-64 Years		Cardiac failure (n/a - Fatal - Results in Death), Cardiac hypertrophy (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Headache (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
477	EU-EC- 10010224173	2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	Male	Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), Abdominal distension (n/a - Recovering/Resolving - Other Medically Important Condition), Aortic dissection (n/a - Fatal - Results in Death), Heat illness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Qualification	Primary Source Country for Regulatory Purposes	Groun	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
478	click or scan EU-EC- 10010224170		2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years	Male	Cardiac failure acute (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Embolism (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
479				Healthcare Professional	Non EEA	65-85 Years	Male	Altered state of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Faeces discoloured (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Gestric cancer (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
480	EU-EC- 10010223769		05	Healthcare Professional	EEA	18-64 Years	Male	Death (0d - Fatal - <u>Results in Death</u>), Palpitations (20d - Fatal - <u>Results in Death</u>), Panic disorder (20d - Fatal - <u>Results in Death</u>), Sinus tachycardia (20d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a - n/a])
481	EU-EC- 10010223144		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
482	<u>click or scan</u> EU-EC- 10010222691		2021-10-	Healthcare Professional	EEA	65-85 Years	Female	Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening), Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening), Inflammatory marker increased (n/a - Not Recovered/Not Resolved - Life Threatening), Pericarditis (n/a - Fata - Results in Death, Life Threatening), Pleural effusion (n/a - Not Recovered/Not Resolved - Life Threatening), Somnolence (n/a - Not Recovered/Not Resolved - Life Threatening)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
483	click or scan EU-EC- 10010222393		2021-10- 05	Non Healthcare Professional	EEA	18-64 Years	Female	COVID-19 (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])
484				Healthcare Professional	EEA	18-64 Years	Female	Dyspnoea (n/a - Not Recovered/Not Resolved -), Eosinophilic myocarditis (n/a - Fatal - Results in Death), Myalgia (n/a - Recovered/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Sudden death (n/a - Fatal - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved -)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
485	click or scan EU-EC-		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Condition aggravated (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypercalcaemia (n/a - Recovering/Resolving -), Hyperkalaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Interstitial lung disease (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Lung neoplasm malignant (n/a - Fatal - Results in Death, Other Medically Important Condition), Renal impairment (n/a - Recovering/Resolving - Other Medically Important Condition)	ALUNBRIG 90 MG [BRIGATINIB] (S - Lung neoplasm malignant - Unknown - [7d - 90mg - Oral - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - n/a - Unknown])
486	click or scan EU-EC- 10010221867		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Condition aggravated (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypercalcaemia (n/a - Recovering/Resolving -), Hyperkalaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Interstitial lung disease (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Lung neoplasm malignant (n/a - Fatal - Results in Death, Other Medically Important Condition), Renal impairment (n/a - Recovering/Resolving - Other Medically Important Condition)	ALUNBRIG 90 MG [BRIGATINIB] (S - Lung neoplasm malignant - Unknown - [7d - 90mg - Oral - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - n/a - Unknown])

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#	EU Local Number		EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group		Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
487	elick or scan EU-EC- 10010221411		2021-10- 05	Healthcare Professional	EEA	18-64 Years	Female	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Ketoacidosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
488	elick or scan EU-EC- 10010221094		2021-10- 05	Healthcare Professional	EEA	18-64 Years		Sudden death (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a])
489	elick or scan EU-EC- 10010220879		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years		COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Incorrect route of product administration (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])
490	EU-EC- 10010220547		2021-10- 05	Non Healthcare Professional	EEA	More than 85 Years		Constipation (n/a - Fatal - Results in Death), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Urinary tract infection (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
491	<u>click or scan</u> EU-EC- 10010220544		2021-10- 05	Non Healthcare Professional	EEA	65-85 Years	Not Specified	Cerebral infarction (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
492	EU-EC- 10010220543		2021-10- 05	Non Healthcare Professional	EEA	18-64 Years	Male	Cardiac death (n/a - Fatal - Results in Death), Exercise tolerance decreased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
493	click or scan EU-EC- 10010220538		2021-10- 05	Non Healthcare Professional	EEA	65-85 Years	Female	Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pulmonary oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
494	click or scan EU-EC- 10010220293		2021-10- 05	Healthcare Professional	Non EEA	More than 85 Years	Female	Ascites (n/a - Unknown - Other Medically Important Condition), Blood albumin increased (n/a - Unknown - Other Medically Important Condition), Blood cholinesterase increased (n/a - Unknown - Other Medically Important Condition), Blood pressure immeasurable (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Unknown - Other Medically Important Condition), Bradycardia (n/a - Unknown - Life Threatening), Cardiac arrest (n/a - Unknown - Life Threatening), Condition aggravated (n/a - Unknown -), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic neoplasm (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Localised oedema (n/a - Unknown -), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pancreatic neoplasm (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Life Threatening), Ventricular tachycardia (n/a - Unknown - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
495	click or scan EU-EC- 10010220288		2021-10- 05	Healthcare Professional	Non EEA	Not Specified		Foetal hypokinesia (n/a - Fatal - Results in Death, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital Anomaly), Umbilical cord abnormality (n/a - Fatal - Results in Death, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
496	EU-EC- 10010220192		2021-10- 05	Healthcare Professional	EEA	More than 85 Years	Male	Aspiration (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a])
497	click or scan EU-EC- 10010219783		05	Healthcare Professional	Non EEA	18-64 Years	Female	Cardiomyopathy (1d - Fatal - Results in Death, Other Medically Important Condition)	PIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
498	EU-EC- 10010219421		2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Female	Palpitations (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
499	EU-EC- 10010219194		2021-10- 05	Healthcare Professional	EEA	65-85 Years		Chest pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myocardial infarction (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved -), Thrombosis (n/a - Fatal - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
500	EU-EC- 10010219058		2021-10- 05	Non Healthcare Professional	Non EEA	65-85 Years	Male	Cerebrovascular accident (1d - Fatal - Results in Death, Other Medically Important Condition), Swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Parenteral]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a]
501	EU-EC- 10010218735		2021-10- 05	Non Healthcare Professional	Non EEA	More than 85 Years	Male	Noninfective encephalitis (194d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Parenteral])
502	EU-EC- 10010218614		2021-10-	Non Healthcare Professional	EEA	65-85 Years	Female	Encephalitis (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a])
503	EU-EC- 10010218315		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Other Medically Important Condition)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - 1/a -
504	EU-EC- 10010218276			Healthcare Professional	Non EEA	More than 85 Years	Female	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abdominal tenderness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Focal peritonitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritoneal perforation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
505	elick or scan EU-EC- 10010218274		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Aspiration (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
506				Healthcare Professional	Non EEA	More than 85 Years	Male	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown -), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
50	7 click or scan EU-EC- 10010218000		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
50	8 EU-EC- 10010217967		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Female	COVID-19 (11d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
50	elick or scan EU-EC- 10010217866		2021-10- 05	Non Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - Results in Death), Haemoptysis (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), Panic attack (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
51	click or scan EU-EC- 10010217729		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years	Male	Aortic thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death. Caused/Prolonged Hospitalisation), Deep vein thrombosis (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Palmin in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Puls	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
51	click or scan EU-EC- 10010217287		2021-10- 05	Non Healthcare Professional	Non EEA	18-64 Years	Male	Myocarditis (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
51	2 click or scan EU-EC- 10010217147		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Acute myocardial infarction (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
51	3 Click or scan EU-EC- 10010217144		2021-10- 05	Healthcare Professional	Non EEA	65-85 Years	Male	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
51	click or scan EU-EC- 10010217138		2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Drug ineffective (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
515	EU-EC- 10010217136		2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
516	<u>click or scan</u> EU-EC- 10010217103		2021-10- 05	Non Healthcare Professional	Non EEA	18-64 Years	Male	Asthenia (n/a - Not Recovered/Not Resolved - Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening), Decreased appetite (n/a - Not Recovered/Not Resolved - Life Threatening), Dizziness (n/a - Not Recovered/Not Resolved - Life Threatening), Head injury (n/a - Not Recovered/Not Resolved - Life Threatening), Head injury (n/a - Not Recovered/Not Resolved - Life Threatening), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening), Immunisation (n/a - Not Recovered/Not Resolved -), Off label use (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])
517	EU-EC- 10010217101		2021-10- 05	Non Healthcare Professional	Non EEA	65-85 Years	Male	Blood glucose abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown -), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
518	EU-EC- 10010216671		2021-10- 05	Healthcare Professional	Non EEA	18-64 Years		Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
519	EU-EC- 10010216583	即此的 和知道 研究语	2021-10- 05	Non Healthcare Professional	Non EEA	Not Specified	Male	Myocardial infarction (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
520	<u>click or scan</u> EU-EC- 10010216571		2021-10- 05	Healthcare Professional	EEA	More than 85 Years	Female	Immunisation (n/a - Unknown -), Off label use (n/a - Unknown -), Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
521	<u>click or scan</u> EU-EC- 10010216477		2021-10- 05	Non Healthcare Professional	EEA	Not Specified	Female	Inappropriate schedule of product administration (n/a - Unknown -), Mineral metabolism disorder (1wk - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Muscle spasms (1wk - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (1wk - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular])
522	EU-EC-		2021-10- 05	Healthcare Professional	EEA	65-85 Years		Asthenia (10d - Fatal - Results in Death), COVID-19 pneumonia (10d - Fatal - Results in Death), Diarrhoea (10d - Fatal - Results in Death), Dyspnoea (10d - Fatal - Results in Death), SARS-CoV-2 test positive (10d - Fatal - Results in Death), Vaccination failure (10d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])
523	<u>click or scan</u> EU-EC- 10010214640		2021-10- 04	Non Healthcare Professional	Non EEA	18-64 Years	Male	Application site discomfort (n/a - Fatal - Results in Death), Brain death (n/a - Fatal - Results in Death), Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - Results in Death), Other Medically Important Condition), Chills (n/a - Fatal - Results in Death), Dengue fever (n/a - Fatal - Results in Death), Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - Results in Death), Dysarthria (n/a - Fatal - Results in Death), Haemorrhagic stroke (n/a - Fatal - Results in Death), Other Medically Important Condition), Headache (n/a - Fatal - Results in Death), Hemiparesis (n/a - Fatal - Results in Death), Other Medically Important Condition), Pain (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Speech disorder (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death), Other Medically Important Condition), Visual impairment (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])

#	EU Local Number	EV Gateway Receipt Date	Primary Source Qualification	Country	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
524	click or scan EU-EC- 10010214548	2021-10- 04	Non Healthcare Professional	Non EEA	18-64 Years	Male	Circulatory collapse (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Memory impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Not applicable - [n/a - n/a - n/a]) COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S] (S - Immunisation - Not applicable - [n/a5mL - Intramuscular]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) COVID-19 WACCINE JANSSEN (AD26.COV2.S) [COVID-19 WARDA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] [COVID-19 MRNA VACCINE MODERNA (CX-024414)] [COVID-19 MRNA VACCINE MODERNA (CX-024414)] [S - COVID-19 immunisation - Not applicable - [1d5mL - Intramuscular]) COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
525	EU-EC- 10010214450	2021-10- 04	Healthcare Professional	EEA	18-64 Years		Death (n/a - Fatal - <u>Results in Death</u>), Fall (n/a - Unknown - <u>Results in Death</u>), Infarction (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a5mL - Intramuscular])
526	EU-EC- 10010214423	2021-10-	Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>), Myocardial infarction (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])
527	EU-EC- 10010214398	2021-10- 04	Non Healthcare Professional	Non EEA	18-64 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
528	EU-EC- 10010214182	2021-10- 04	Healthcare Professional	EEA	18-64 Years	Male	Sudden death (1d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d5mL - Intramuscular])
529	EU-EC- 10010213953	2021-10- 04	Healthcare Professional	Non EEA	More than 85 Years	Female	Dyspnoea (n/a - Fatal - Results in Death , Life Threatening)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
530	click or scan EU-EC-	2021-10- 04	Healthcare Professional	Non EEA	More than 85 Years	Female	Asphyxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
531	EU-EC- 10010213893	2021-10- 04	Healthcare Professional	EEA	65-85 Years	Male	Chronic obstructive pulmonary disease (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
532	EU-EC- 10010213756		Healthcare Professional	Non EEA	18-64 Years	Male	Thrombocytopenia (n/a - Fatal - <u>Results in Death</u>), Thrombosis (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 - Unknown - [n/a - n/a - Intramuscular])
533	EU-EC- 10010213610		Healthcare Professional	Non EEA	Not Specified		Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number		EV Gateway Receipt Date	O1:6:4:	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
534	elick or scan EU-EC- 10010213472	THE TANK DESCRIPTION OF	2021-10- 04	Healthcare Professional	Non EEA	18-64 Years	Male	Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Limb injury (n/a - Unknown -)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
535	EU-EC- 10010213288		04	Healthcare Professional	Non EEA	65-85 Years	Female	Apnoca (n/a - Fatal - <u>Results in Death</u>), Respiratory arrest (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [DONEPEZIL HYDROCHLORIDE] (S - n/a - Unknown - [n/a - n/a - Oral])
536	EU-EC- 10010213161	INCREMENTS OF	2021-10- 04	Non Healthcare Professional	Non EEA	65-85 Years	Female	Acute myocardial infarction (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S-n/a-Unknown-[n/a- n/a-Intramuscular])
537	EU-EC- 10010213106		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	Acute kidney injury (n/a - Fatal - Results in Death), Aortic stenosis (n/a - Fatal - Results in Death), Colitis ischaemic (n/a - Fatal - Results in Death), Embolism (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
538	EU-EC- 10010213103	(E1) 120 LOS M. 450	2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>), Dyspnoea (n/a - Fatal - <u>Results in Death</u>), Thrombosis (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Unknown - [n/a - n/a - Intramuscular])
539	EU-EC- 10010212090	E1:32 (49.45.45)	04	Non Healthcare Professional	Non EEA	18-64 Years	Female	Thrombosis (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
540	EU-EC- 10010211541		2021-10- 04	Non Healthcare Professional	EEA	65-85 Years	Female	Subarachnoid haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a])
541	EU-EC- 10010211319		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	Asthenia (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>), Dyspnoea (n/a - Fatal - <u>Results in Death</u>), Nasopharyngitis (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
542	click or scan		2021-10-	Healthcare Professional	Non EEA	18-64 Years	Female	Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Dizziness (1d - Unknown -)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
543	click or scan EU-EC- 10010211048		2021-10- 04	Non Healthcare Professional	EEA	18-64 Years	Male	Suspected COVID-19 (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])

#	EU Local Number	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
544	EU-EC- 10010211045	2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	Abdominal pain (n/a - Fatal - Results in Death, Life Threatening), Back pain (n/a - Fatal - Results in Death, Life Threatening)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
545	EU-EC- 10010210960	2021-10- 04	Healthcare Professional	Non EEA	More than 85 Years		Cardiac failure congestive (n/a - Fatal - Results in Death, Other Medically Important Condition), Constipation (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
546	elick or scan EU-EC- 10010210710	2021-10- 04	Non Healthcare Professional	Non EEA	18-64 Years	Female	Brain death (n/a - Unknown - Life Threatening), Cerebral haemorrhage (n/a - Fatal - Results in Death), Cerebral thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Migraine (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved -)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
547	EU-EC- 10010210617	2021-10- 04	Healthcare Professional	EEA	More than 85 Years	Female	Acute pulmonary oedema (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
548	EU-EC- 10010210611	2021-10- 04	Healthcare Professional	EEA	More than 85 Years	Male	Cardiac arrest (n/a - Fatal - Results in Death), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
549	elick or scan EU-EC- 10010210610	2021-10- 04	Non Healthcare Professional	EEA	18-64 Years	Female	Death (1d - Fatal - Results in Death), Therapeutic response decreased (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
550	EU-EC- 10010210606	2021-10- 04	Healthcare Professional	EEA	65-85 Years	Female	Aortic thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal artery thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular])
551	EU-EC- 10010210576	2021-10- 04	Healthcare Professional	EEA	More than 85 Years	Male	Vaccination failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
552	click or scan EU-EC- 10010210538	2021-10- 04	Non Healthcare Professional	EEA	More than 85 Years	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])
553	click or scan EU-EC- 10010210458		Healthcare Professional	EEA	18-64 Years	Male	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])
554	elick or scan EU-EC- 10010210450	2021-10- 04	Healthcare Professional	EEA	More than 85 Years	Male	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number	ICSR Form	Gateway Receipt Date	Primary Source	Primary Source Country for Regulatory Purposes	Age C	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
555	EU-EC- 10010210326		2021-10- 04	Healthcare Professional	EEA	18-64 Years	Female	Myocardial infarction (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
556				Healthcare Professional	Non EEA	65-85 Years	Male	Cardiac arrest (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - Results in Death), Electrocardiogram change (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypoxic-ischaemic encephalopathy (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Physical deconditioning (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Ventricular arrhythmia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Ventricular fibrillation (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
557	click or scan EU-EC- 10010209655		04	Healthcare Professional	Non EEA	65-85 Years	Male	Arthralgia (n/a - Fatal - <u>Results in Death</u>), Cough (n/a - Fatal - <u>Results in Death</u>), Pain (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
558	EU-EC- 10010209585		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	Acute myocardial infarction (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
559	click or scan		2021-10- 04	Healthcare Professional	Non EEA	More than 85 Years	Female	Disease recurrence (n/a - Fatal - Results in Death), Castric ulcer haemorrhage (n/a - Fatal - Results in Death), Shock haemorrhagic (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
560	EU-EC- 10010208946		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years		Altered state of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown -), Eating disorder (n/a - Fatal - Results in Death, Life Threatening), Heart rate increased (n/a - Unknown -), Hepatic function abnormal (n/a - Fatal - Results in Death), Oedema (n/a - Unknown -), Pallor (n/a - Unknown -), Pyrexia (n/a - Fatal - Results in Death), Other Medically Important Condition), Respiratory arrest (n/a - Fatal - Results in Death), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
561	EU-EC- 10010208830		2021-10- 04	Non Healthcare Professional	Non EEA	65-85 Years	Female	General physical health deterioration (n/a - Fatal - Results in Death), Haemoptysis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
562	elick or scan EU-EC- 10010208820		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	Decreased activity (n/a - Fatal - Results in Death), Urinary tract infection (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
563	click or scan EU-EC- 10010208807		04	Healthcare Professional	Non EEA	65-85 Years	Male	Blood pressure decreased (n/a - Unknown -), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Heart rate decreased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
564	click or scan EU-EC- 10010208806		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Female	Myocardial infarction (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])

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#	EU Local Number	EV Gateway Receipt Date	Primary Source Qualification	Country	Age	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
565	click or scan EU-EC- 10010208800		Healthcare Professional	Non EEA	65-85 Years	Male	Acute leukaemia (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Weight increased (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
566	EU-EC- 10010208787	2021-10- 04	Healthcare Professional	Non EEA	18-64 Years	Female	Brain oedema (n/a - Fatal - Results in Death), Cardiovascular insufficiency (n/a - Fatal - Results in Death), Myocardial ischaemia (n/a - Fatal - Results in Death), Pulmonary artery thrombosis (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
567	EU-EC- 10010208571	2021-10- 04	Healthcare Professional	EEA	18-64 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a])
568	elick or scan EU-EC- 10010208120	2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Female	Anosmia (4d - Fatal - Results in Death), Dizziness (4d - Fatal - Results in Death), Pain (4d - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
569	click or scan EU-EC- 10010207895	2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	Cough (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
570	click or scan	2021-10- 04	Non Healthcare Professional	EEA	More than 85 Years		Brain stem infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	ANTICOAGULANS (BLOEDVERDUNNER) [NOT AVAILABLE] (S - Product used for unknown indication - Drug withdrawn - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
571	EU-EC- 10010207601	2021-10- 04	Healthcare Professional	EEA	18-64 Years	Male	Chest pain (n/a - Fatal - Results in Death, Life Threatening), Diabetic ketoacidosis (n/a - Fatal - Results in Death, Life Threatening), Myocardial infarction (1d - Fatal - Results in Death, Life Threatening), Vomiting (n/a - Fatal - Results in Death, Life Threatening)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
572	EU-EC- 10010207541	04	Healthcare Professional	Non EEA	65-85 Years	Male	Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
573	EU-EC- 10010206746	04	Healthcare Professional		More than 85 Years	Male	Cerebral haemorrhage (2d - Fatal - Results in Death), Cerebral infarction (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a])
574	EU-EC- 10010206501	2021-10- 04	Non Healthcare Professional	EEA	65-85 Years	Female	Chest pain (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

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EU Local Number	ICSR Form	EV Gateway Receipt Date	O 1: C 4:	Primary Source Country for Regulatory Purposes	Age	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
click or scan EU-EC- 10010206468		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Female	Important Condition), Pleural effusion (n/a - Unknown -), Pneumomediastinum (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pneumothorax (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Subcutaneous emphysema (n/a - Unknown -), Thrombophlebitis superficial (n/a - Unknown -), Thrombosis (n/a - Unknown - Other Medically Important Condition),	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
EU-EC-		2021-10- 04	Healthcare Professional	EEA	18-64 Years	Male	Blood pressure decreased (0d - Fatal - Results in Death), Cardiac arrest (0d - Fatal - Results in Death), Feeling abnormal (0d - Fatal - Results in Death), Hypoaesthesia oral (0d - Fatal - Results in Death), Seizure (0d - Fatal - Results in Death), Sluggishness (0d - Fatal - Results in Death), Tonic convulsion (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])
EU-EC-		2021-10- 04	Healthcare Professional	Non EEA	More than 85 Years		Lung neoplasm malignant (n/a - Fatal - Results in Death, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
LC-LC-		2021-10- 04	Healthcare Professional	Non EEA	18-64 Years	Male	Cardiac failure acute (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
EU-EC-		04	Healthcare Professional	Non EEA	65-85 Years	Female	Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Generalised oedema (n/a - Unknown - Other Medically Important Condition), Hypokalaemia (n/a - Unknown - Other Medically Important Condition), Liver disorder (n/a - Unknown - Other Medically Important Condition), Malnutrition (n/a - Unknown - Other Medically Important Condition), Malnutrition (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Prexia (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Respiratory alkalosis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]), [EDARAVONE] (S - Cerebral infarction - Unknown - [n/a - 60mg - n/a]), [PAZUFLOXACIN MESILATE] (S - n/a - Unknown - [n/a - 1g - n/a])
EU-EC- 10010206003		2021-10- 04	Non Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
EU-EC-		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years		Brain stem haemorrhage (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
EU-EC- 10010205632			Healthcare Professional	EEA	18-64 Years	Female		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
	click or scan EU-EC- 10010206468 click or scan EU-EC- 10010206068 click or scan EU-EC- 10010206003 click or scan EU-EC- 10010206003 click or scan EU-EC- 10010206003	Click or scan	Click or scan Click or sca	Click or scan	EU Local Number Click or scan Click or scan	EU Local Number ICSR Form Regulatory Primary Source Country for Group Purposes Click or scan EU-EC-10010206446 Click or scan EU-EC-10010206406 Click or scan EU-EC-10010206406 Click or scan EU-EC-10010206006 Click or scan EU-EC-10010206008 Click or scan EU-	EU Local Number ICSR Form Receipt Date Primary Source Qualification Regulatory Purposes 2021-10- Healthcare 10010206468 Click or scan 10010206468 Click	But Lead Number CSR Form Control Qualification Property Qualification Qualification Qualification Property Qualification Qual

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#	EU Local Number		Gateway	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Age	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
583	elick or scan EU-EC- 10010205578		2021-10- 04	Non Healthcare Professional	Non EEA	Not Specified	Female	Cardiac failure (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Myocarditis (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
584		高級	04	Healthcare Professional	EEA	65-85 Years	Male	Castrointestinal haemorrhage (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a3mL - n/a])
585	EU-EC- 10010205541		2021-10-	Healthcare Professional	EEA	18-64 Years	Female	Ruptured cerebral aneurysm (2d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
586	EU-EC- 10010205490	E102646245451	04	Non Healthcare Professional	EEA	65-85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
587	EU-EC- 10010205483	TELESCOPE SECTION	2021-10- 04	Non Healthcare Professional	EEA	More than 85 Years	Male	Multiple organ dysfunction syndrome (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a - n/a])
588	EU-EC- 10010205470		2021-10- 04	Non Healthcare Professional	EEA	More than 85 Years	Male	Coma (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
589	EU-EC- 10010205461		2021-10-	Non Healthcare Professional	EEA	18-64 Years	Male	Colon cancer metastatic (n/a - Fatal - <u>Results in Death</u>)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a])
590	click or scan EU-EC- 10010205460		2021-10-	Non Healthcare Professional	EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Liver function test abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
591	elick or scan EU-EC- 10010205251			Healthcare Professional	Non EEA	18-64 Years		Asthenia (n/a - Fatal - <u>Results in Death</u>), Dyspnoea (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular])
592	EU-EC- 10010205229		2021-10- 04	Healthcare Professional	Non EEA	65-85 Years	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - Results in Death), Thrombocytopenic purpura (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])

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#	EU Local Number		Receipt Date		Primary Source Country for Regulatory Purposes	Croup	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
593	EU-EC- 10010204416		2021-10- 04	Non Healthcare Professional	Non EEA	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
594	click or scan EU-EC- 10010203960			Healthcare Professional	Non EEA	More than 85 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Localised infection (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), [ENZALUTAMIDE] (S - Prostate cancer - Not applicable - [302d - 160mg - Oral])
595	EU-EC- 10010203748	ELIZAGE KARA	04	Healthcare Professional	Non EEA	18-64 Years	Female	Blood blister (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death Other Medically Important Condition), Epistaxis (n/a - Recovered/Resolved - Other Medically Important Condition), Haematemesis (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - Results in Death, Other Medically Important Condition), Petechiae (n/a - Unknown - Other Medically Important Condition), Rhinitis (n/a - Recovered/Resolved - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
596	EU-EC- 10010203718		2021-10- 04	Healthcare Professional	Non EEA	More than 85 Years	Female	Malaise (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
597	EU-EC- 10010201118		02	Non Healthcare Professional	EEA	65-85 Years	Male	Dermatitis bullous (n/a - Fatal - <u>Results in Death</u>), Skin lesion (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])
598	EU-EC- 10010201100		2021-10- 02	Non Healthcare Professional	EEA	More than 85 Years	Female	Cerebrovascular accident (22d - Fatal - Results in Death), Pyrexia (22d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
599	EU-EC- 10010201073		2021-10- 02	Non Healthcare Professional	EEA	More than 85 Years	Male	General physical health deterioration (74d - Fatal - Results in Death), Pneumonia (74d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
600	click or scan EU-EC- 10010200992		2021-10- 02	Non Healthcare Professional	EEA	18-64 Years	Male	Fatigue (n/a - Fatal - Results in Death), Nasopharyngitis (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Sneezing (n/a - Fatal - Results in Death), Sxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
601	click or scan EU-EC- 10010200987		2021-10- 02	Healthcare Professional	EEA	18-64 Years	Male	COVID-19 pneumonia (3d - Fatal - <u>Results in Death</u>), Drug ineffective (3d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])
602	click or scan		2021-10- 02	Healthcare Professional	EEA	65-85 Years	Male	Death (0d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])

		EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
6	03	EU-EC- 10010200808		2021-10- 02	Non Healthcare Professional	EEA	65-85 Years	Male	Asthenia (n/a - Fatal - <u>Results in Death</u>), Pulmonary embolism (n/a - Fatal - <u>Results in Death</u>), Vomiting (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
6	04	click or scan EU-EC- 10010200783		2021-10- 02	Non Healthcare Professional	EEA	65-85 Years	Male	CSF glucose abnormal (n/a - Fatal - <u>Results in Death</u>), Cerebrovascular accident (n/a - Fatal - <u>Results in Death</u>)	immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
6	05	EU-EC- 10010200745		2021-10- 02	Non Healthcare Professional	EEA	65-85 Years	Female	Ruptured cerebral aneurysm (0d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
6	06	<u>click or scan</u> EU-EC- 10010200564		2021-10- 02	Non Healthcare Professional	Non EEA	65-85 Years	Female	Aortic dissection (2d - Fatal - Results in Death, Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular])
6	07	<u>click or scan</u> EU-EC- 10010199120		2021-10- 02	Non Healthcare Professional	EEA	65-85 Years	Male	Anaemia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Lymphoma (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved -), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
6	08	<u>click or scan</u> EU-EC- 10010198948		2021-10- 02	Non Healthcare Professional	EEA	65-85 Years	Female	Eye injury (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])
6	09	<u>click or scan</u> EU-EC- 10010200399		2021-10- 01	Healthcare Professional	Non EEA	18-64 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
6	10	elick or scan EU-EC- 10010200398		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	Aortic stenosis (n/a - Fatal - Results in Death), Cardiopulmonary failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
6	11	click or scan EU-EC- 10010200368		2021-10- 01	Healthcare Professional	EEA	18-64 Years	Female	Administration site pain (2d - Recovered/Resolved - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Vunknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
612	elick or scan EU-EC- 10010200285		2021-10- 01	Non Healthcare Professional	EEA	More than 85 Years		Haematemesis (0d - Fatal - <u>Results in Death</u>), Upper gastrointestinal haemorrhage (0d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
613	elick or scan EU-EC- 10010200283		2021-10- 01	Non Healthcare Professional	EEA	65-85 Years	Female	Malaise (n/a - Unknown -), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death) Cerebrovascular accident (62d - Fatal - Results in Death), Headache (62d - Fatal - Results in Death), Neoplasm (62d - Fatal - Results in Death)	·COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
614	elick or scan EU-EC- 10010200281		2021-10- 01	Non Healthcare Professional	EEA	65-85 Years	Female	Cerebrovascular accident (62d - Fatal - <u>Results in Death</u>), Headache (62d - Fatal - <u>Results in Death</u>), Neoplasm (62d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
615	EU-EC- 10010200276		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Asthenia (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
616	EU-EC- 10010200247		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Cough (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
617	elick or scan EU-EC- 10010200095		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Marasmus (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
618	click or scan EU-EC- 10010199964		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	Acute respiratory failure (24d - Fatal - Results in Death, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chronic respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (n/a - Fatal - Results in Death), Decubitus ulcer (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Hypercapnia (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Other Medically Important Condition), Mental status changes (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death), Other Medically Important Condition), Snock (n/a - Fatal - Results in Death), Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - Results in Death), Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
619	elick or scan EU-EC- 10010199951		2021-10- 01	Healthcare Professional	Non EEA	18-64 Years	Male	Fatigue (14d - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
620	EU-EC- 10010199923		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	FOOLID 10 VA COD E LA JOSEN (ADDA COND ON CO

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
62	click or scan EU-EC- 10010199555		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	Concomitant disease progression (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug interaction (n/a - Unknown -), Fatigue (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fluid intake reduced (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [CANDESARTAN CILEXETIL] (I - n/a - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE, Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]), [SPIRONOLACTONE] (I - n/a - Not applicable - [n/a - n/a - n/a]), [WARFARIN SODIUM] (I - n/a - Not applicable - [n/a - n/a - n/a])
62	click or scan 2 EU-EC- 10010199391		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Agitation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anticoagalant therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anxiety (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bilevel positive airway pressure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blood gases (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), CovID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confisional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confisional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nechanical ventilation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion), Pulmona	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a - Intramuscular]), [CANDESARTAN CILEXETIL] (1 - n/a - Not applicable - [n/a - n/a - Oral]), [DILTIAZEM HYDROCHLORIDE] (1 - n/a - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]), [SPIRONOLACTONE] (1 - n/a - Not applicable - [n/a - n/a - n/a]), [WARFARIN SODIUM] (I - n/a - Not applicable - [n/a - n/a - n/a]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR1)
62	EU-EC- 10010198720		2021-10- 01	Non Healthcare Professional	Non EEA	Not Specified	Female	Foetal hypokinesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])
62	click or scan EU-EC- 10010198709		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Cardiovascular insufficiency (n/a - Fatal - <u>Results in Death</u>), Hyperplasia (n/a - Fatal - <u>Results in Death</u>), Ischaemic cardiomyopathy (n/a - Fatal - <u>Results in Death</u>), Pulmonary oedema (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
62	click or scan EU-EC- 10010198677		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Asthma (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR])
62	click or scan EU-EC- 10010198454		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	Cerebral disorder (n/a - Fatal - <u>Results in Death</u>), Hydrocephalus (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

Filtered by "Seriousness Criteria": "Results in Death"

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Country	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
627	EU-EC- 10010198342		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Female	Asthenia (n/a - Fatal - <u>Results in Death</u>), Decreased appetite (n/a - Fatal - <u>Results in Death</u>), Dyspnoea (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
628			2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasopharyngitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
629	EU-EC- 10010198228			Healthcare Professional	Non EEA	18-64 Years	Female	Arrhythmia (n/a - Fatal - Results in Death, Other Medically Important Condition), Breath sounds abnormal (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
630	EU-EC- 10010198201		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
631	EU-EC- 10010198145		2021-10- 01	Healthcare Professional	EEA	65-85 Years	Female	Joint swelling (n/a - Recovering/Resolving -), Pancreatitis acute (n/a - Not Recovered/Not Resolved -), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
632	EU-EC- 10010198069		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Cardiac failure congestive (n/a - Fatal - Results in Death), Small cell lung cancer (n/a - Unknown - Other Medically Important Condition), Trismus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
633	click or scan EU-EC- 10010197986			Non Healthcare Professional	Non EEA	18-64 Years	Male	Dyslexia (n/a - Unknown - Other Medically Important Condition), Intellectual disability (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown -), Mental disorder (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), Retinal degeneration (n/a - Unknown - Other Medically Important Condition), Retinal detachment (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
634	EU-EC- 10010197982		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	Cardiovascular disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
635	EU-EC- 10010197942		2021-10- 01	Non Healthcare Professional	Non EEA	18-64 Years	Male	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -), Pulmonary embolism (n/a - Fatal - Results in Death), Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
636	click or scan		2021-10- 01	Non Healthcare Professional	EEA	18-64 Years	Male	Cerebral thrombosis (n/a - Fatal - Results in Death), Cerebral thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (4d - Recovered/Resolved -), Hemiparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])

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i		EU Local Number		EV Gateway Receipt Date	O 11.00 41	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
6.	37	click or scan EU-EC- 10010197829		2021-10- 01	Healthcare Professional	EEA	More than 85 Years		Asthma (n/a - Unknown -), COVID-19 pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Hip fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown -), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
6.	38	click or scan EU-EC- 10010197816		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
6.	39	click or scan			Healthcare Professional	EEA	18-64 Years	Male	Cavernous sinus thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
6-	10	EU-EC-10010197468		2021-10- 01	Healthcare Professional	Non EEA	18-64 Years	Male	Cardiac tamponade (n/a - Fatal - Results in Death), Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspepsia (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S-n/a - Not applicable - [1d-n/a - Intramuscular])
6-	1 1	EU-EC-10010197233		2021-10- 01	Non Healthcare Professional	Non EEA	Not Specified	Male	Cardiac failure congestive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
6-	12	click or scan EU-EC- 10010196652			Non Healthcare Professional	Non EEA	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
6-	13	click or scan EU-EC- 10010196494		2021-10- 01	Non Healthcare Professional	EEA	Not Specified	Male	Embolism (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S-n/a - Unknown - [n/a - n/a - Intramuscular])
6-	14		TELESCOPE AND ADDRESS OF THE PERSON OF THE P	2021-10- 01	Non Healthcare Professional	EEA	65-85 Years	Female	Acute myocardial infarction (2d - Fatal - Results in Death), Coronary artery thrombosis (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
6-	15	click or scan EU-EC- 10010196187		2021-10- 01	Non Healthcare Professional	Non EEA	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
6	16				Healthcare Professional	Non EEA	65-85 Years	Female	Subarachnoid haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
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#	EU Local Number		EV Gateway Receipt Date	Source	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
647	THE CT COLLET		2021-10- 01	Healthcare Professional	EEA	65-85 Years	Female	Death (n/a - Fatal - Results in Death), Epilepsy (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown -), Infection (n/a - Unknown -), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
648	click or scan EU-EC- 10010195770		2021-10- 01	Healthcare Professional	Non EEA	18-64 Years	Female	Cough (11d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (11d - Unknown - Other Medically Important Condition), Pyrexia (11d - Unknown - Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
649	<u>click or scan</u> EU-EC- 10010195640		2021-10- 01	Healthcare Professional	EEA	More than 85 Years	Female	Cerebrovascular accident (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
650	EU-EC- 10010195631		2021-10- 01	Healthcare Professional	EEA	18-64 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
651		国(A)A)A(A)A(A)A(A)	2021-10- 01	Non Healthcare Professional	EEA	18-64 Years	Female	Foetal death (n/a - Fatal - <u>Results in Death</u>), Retroplacental haematoma (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
652	<u>click or scan</u> EU-EC- 10010195557		2021-10- 01	Healthcare Professional	EEA	65-85 Years	Male	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
653	EU-EC- 10010195552		2021-10- 01	Healthcare Professional	EEA	More than 85 Years	Female	Asthenia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Not Recovered/Not Resolved -)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
654	click or scan EU-EC- 10010195537	E103246245454	2021-10- 01	Healthcare Professional	EEA	65-85 Years	Male	Ruptured cerebral aneurysm (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [D,L-LYSINE ACETYLSALICYLATE] (S - Thrombosis prophylaxis - Not applicable - [n/a - 75mg - Oral])
655	EU-EC- 10010195522		2021-10- 01	Healthcare Professional	EEA	18-64 Years	Female	Cardiac arrest (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
656	click or scan EU-EC- 10010195455		2021-10- 01	Healthcare Professional	EEA	65-85 Years	Male	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [40d - 2 {DF} - Intramuscular])

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#		mber	CSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
65	7 E	FILEC-	STERROR TERROR DE PARTI		Healthcare Professional	EEA	65-85 Years	Male	Vaccination failure (27d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular])
65	8 E			2021-10- 01	Healthcare Professional	EEA	65-85 Years	Male	Cardiac failure acute (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
65	9 E	FILEC-		2021-10- 01	Non Healthcare Professional	EEA	65-85 Years	Male	Arthralgia (n/a - Unknown -), Death (n/a - Fatal - <u>Results in Death</u>), Malaise (n/a - Unknown -), Off label use (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
60	0 E	EU-EC- 010195249		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Arthralgia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cait inability (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Joint effusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Walaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
60	1 E	ck or scan EU-EC- 010195036		2021-10- 01	Non Healthcare Professional	Non EEA	65-85 Years	Male	Adverse event (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Chronic obstructive pulmonary disease (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Joint stiffness (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Malaise (n/a - Unknown -), Myocardial infarction (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
60	2 H	ck or scan			Healthcare Professional	Non EEA	More than 85 Years	Female	Asthenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
66	3 E 100	ck or scan EU-EC- 010194695		2021-10- 01	Healthcare Professional	EEA	65-85 Years	Female	Vaccination failure (27d - Fatal - Results in Death) Arthralgia (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -), Off label use (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -) Arthralgia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cair inability (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Variety (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Variety (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation) Adverse event (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Joint stiffness (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Joint stiffness (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Malaise (n/a - Unknown -), Myocardial infarction (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation) Asthenia (n/a - Fatal - Results in Death), Life Threatening, Caused/Prolonged Hospitalisation) Cardiomegaly (n/a - Fatal - Results in Death), Deep vein thrombosis (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death) Cardiomegaly (n/a - Fatal - Results in Death), Caused/Prolonged Hospitalisation), Pulmonary fibrosis (n/a - Fatal - Results in Death), Caused/Prolonged Hospitalisation), Pulmonary fibrosis (n/a - Fatal - Results in Death), Caused/Prolonged Hospitalisation), Pulmonary fibrosis (n/a - Fatal - Results in Death), Chest discomfort (n/a - Unknown -), Myocardial ischaemia (n/a - Fatal - Results in Death), Myocardialischienia (n/a - Fatal - Results in Death), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])
66	4 E	ck or scan EU-EC- 010194348			Healthcare Professional	Non EEA	65-85 Years	Male	Lung opacity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary fibrosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
66	5 E	ck or scan		2021-10- 01	Non Healthcare Professional	Non EEA	65-85 Years	Male	Cardiomegaly (n/a - Fatal - Results in Death), Chest discomfort (n/a - Unknown -), Myocardial ischaemia (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death), Pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
66	6 E	ck or scan			Healthcare Professional	Non EEA	65-85 Years		Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death), Myocardial rupture (n/a - Fatal - Results in Death), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])

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#	Number	ICSK FORM	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
667	EU-EC- 10010194252		2021-10- 01	Healthcare Professional	Non EEA	More than 85 Years	Male	Blood pressure decreased (n/a - Unknown -), Chronic respiratory failure (n/a - Fatal - Results in Death), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
668	EU-EC- 10010193874		2021-10- 01	Non Healthcare Professional	EEA	18-64 Years	Female	Chills (5d - Recovered/Resolved -), Hyperhidrosis (5d - Recovered/Resolved -), Pulmonary embolism (7d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
669	click or scan EU-EC- 10010193866		2021-10- 01	Non Healthcare Professional	EEA	18-64 Years	Male	Cerebral venous sinus thrombosis (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a - n/a])
670	EU-EC- 10010193649			Healthcare Professional	EEA	More than 85 Years	Female	Death (0d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
671	click or scan EU-EC- 10010192809			Healthcare Professional	Non EEA	65-85 Years	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])
672	EU-EC- 10010192671			Healthcare Professional	EEA	More than 85 Years	Female	Cardiac failure acute (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
673	<u>click or scan</u> EU-EC- 10010192351			Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ileus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [DONEPEZIL] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular])
674	EU-EC- 10010192098		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Female	Respiratory arrest (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [DONEPEZIL] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Oral])
675	EU-EC- 10010192036			Healthcare Professional	Non EEA	65-85 Years		COVID-19 (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death), Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular])
676	EU-EC- 10010191908			Healthcare Professional	Non EEA	65-85 Years	Male	Atrial fibrillation (1d - Recovered/Resolved - Other Medically Important Condition), Death (0d - Fatal - Results in Death, Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	O 1: C 4:	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
67	click or scan EU-EC- 10010191740	E1:4776676444	01	Healthcare Professional	EEA	65-85 Years	Female	COVID-19 immunisation (n/a - Unknown -), General physical health deterioration (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
67	EU-EC- 10010191582		2021-10- 01	Non Healthcare Professional	EEA	65-85 Years	Female	Fatigue (n/a - Not Recovered/Not Resolved -), Pneumonia (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
67	EU-EC- 10010191135	INCAMENTARY.	01	Healthcare Professional	Non EEA	More than 85 Years		Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
68	EU-EC- 10010191039		2021-10- 01	Non Healthcare Professional	Non EEA	Not Specified	Male	Death (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
68	elick or scan EU-EC- 10010190920		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Female		COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
68	elick or scan EU-EC- 10010190815		2021-10- 01	Non Healthcare Professional	Non EEA	Not Specified	Male	Autoimmune disorder (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA · (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
68	click or scan B EU-EC- 10010190174			Non Healthcare Professional	Non EEA	More than 85 Years	Male	Cardiac disorder (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Interchange of vaccine products (n/a - Unknown -), Off label use (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
68	click or scan EU-EC- 10010190146		01	Healthcare Professional	Non EEA	Not Specified	Male	Myocardial ischaemia (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
68	10010190135		2021-10- 01	Non Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
68	click or scan EU-EC- 10010190055		2021-10- 01	Healthcare Professional	EEA	18-64 Years	Male	Cardiac arrest (2d - Fatal - <u>Results in Death</u>), Headache (n/a - Fatal - <u>Results in Death</u>), Malaise (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>), Sudden death (2d - Fatal - <u>Results in Death</u>)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])

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	EU Local Number	ICSR Form	Gateway Receipt	Primary Source Qualification	Source Country for Regulatory	Age	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
87	click or scan EU-EC- 10010189900		2021-10- 01		Non EEA	More than 85 Years	Male	Respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
188	EU-EC- 10010189732		2021-10- 01	Non Healthcare Professional	Non EEA	18-64 Years	Male	Blood pressure increased (n/a - Unknown -), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved -), Patigue (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Oxygen saturation decreased (n/a - Unknown -), Pain (n/a - Not Recovered/Not Resolved -), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a - n/a])
89	click or scan EU-EC- 10010189706	型域型 軟塊質 衛球衛	2021-10- 01	Non Healthcare Professional	Non EEA	65-85 Years	Male	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
90	elick or scan EU-EC- 10010189571		2021-10- 01	Healthcare Professional	Non EEA	18-64 Years	Male	Adverse event following immunisation (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
91	click or scan EU-EC-		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Female	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
92	click or scan EU-EC- 10010189490		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])
93	EU-EC- 10010189485		2021-10- 01	Healthcare Professional	Non EEA	65-85 Years	Female	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - Results in Death, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - Results in Death, Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
94	click or scan EU-EC- 10010189266		2021-10- 01		EEA	More than 85 Years	Male	COVID-19 pneumonia (5d - Fatal - <u>Results in Death</u>), Drug ineffective (5d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])
95	click or scan EU-EC- 10010189190		2021-10- 01		EEA	18-64 Years	Female	Cardiac arrest (0d - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])
96	click or scan EU-EC- 10010189185		2021-10- 01			65-85 Years		Asthenia (29d - Fatal - Results in Death), Groin pain (29d - Fatal - Results in Death), Leukopenia (29d - Fatal - Results	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
	# 87 888 89 90 91 92 93 94 95	# Number click or scan EU-EC- 10010189900 click or scan EU-EC- 10010189732 click or scan EU-EC- 10010189706 click or scan EU-EC- 10010189571 click or scan EU-EC- 10010189516 click or scan EU-EC- 10010189490 click or scan EU-EC- 10010189190	# Number CSR Form 87	# BU Local Number ICSR Form Raceipt 87		Number ICSR Form Cateway Source Country Purposes			Sick of Sam Sunday Control Con

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Qualification	Primary Source Country for Regulatory Purposes	Croup	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
697	EU-EC- 10010187355		2021-10- 01	Non Healthcare Professional	EEA	65-85 Years	Male	Cerebral haemorrhage (2d - Fatal - <u>Results in Death</u>), Coma (2d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular])
698	click or scan EU-EC- 10010187348		2021-10- 01	Non Healthcare Professional	EEA	More than 85 Years	Female	Thrombophlebitis (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mg - Intramuscular])
699	<u>click or scan</u> EU-EC- 10010187346		2021-10- 01	Non Healthcare Professional	EEA	65-85 Years	Female	Abdominal distension (n/a - Fatal - Results in Death), Asthenia (n/a - Fatal - Results in Death), Embolism (n/a - Fatal - Results in Death), Ischaemia (n/a - Fatal - Results in Death), Retching (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
700	EU-EC- 10010187326		2021-10- 01	Healthcare Professional	EEA	65-85 Years	Male	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a5mL - Intramuscular])
701	EU-EC- 10010187325		2021-10- 01	Non Healthcare Professional	EEA	More than 85 Years	Female	Back pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])
702	EU-EC- 10010187304		2021-10- 01	Healthcare Professional	EEA	More than 85 Years	Male	Agitation (0d - Fatal - Results in Death), Dyspnoea (0d - Fatal - Results in Death), Pulmonary embolism (0d - Fatal - Results in Death), Pyrexia (0d - Fatal - Results in Death), Somnolence (0d - Fatal - Results in Death), Tachypnoea (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a])
703	EU-EC- 10010188338		2021-09- 30	Healthcare Professional	Non EEA	18-64 Years	Male	Acute coronary syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
704	<u>click or scan</u> EU-EC- 10010187957		2021-09- 30	Healthcare Professional	Non EEA	65-85 Years		Carbon monoxide poisoning (n/a - Fatal - Results in Death), Cervical vertebral fracture (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Rib fracture (n/a - Fatal - Results in Death), Spinal cord haemorrhage (n/a - Fatal - Results in Death), Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
705	EU-EC- 10010187739			Healthcare Professional	Non EEA	18-64 Years	Male	Eye pain (n/a - Unknown -), Headache (n/a - Unknown -), Intracranial pressure increased (n/a - Fatal - Results in Death, Other Medically Important Condition), Nausea (n/a - Unknown -), Neurosis (n/a - Fatal - Results in Death), Vomiting (n/a - Unknown -)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - Intramuscular])
706	click or scan EU-EC- 10010187733		2021-09- 30	Non Healthcare Professional	Non EEA	More than 85 Years	Male	Asthenia (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Eye disorder (n/a - Unknown -), Illness (n/a - Unknown - Other Medically Important Condition), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown -), Thrombosis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [VITAMINS NOS] (S - n/a - Unknown - [n/a - n/a - n/a])
707	<u>click or scan</u> EU-EC- 10010187052			Healthcare Professional	Non EEA	18-64 Years	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (2d - Fatal - Results in Death), Tremor (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number		Gateway	Primary Source Qualification	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
708	EU-EC- 10010186973		2021-09- 30	Non Healthcare Professional	Non EEA	Not Specified	Female	Death (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
709	10010186945		2021-09- 30	Non Healthcare Professional	EEA	65-85 Years	Female	Intestinal ischaemia (n/a - Fatal - <u>Results in Death</u>), Sepsis (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a - n/a])
710	EU-EC- 10010186885		2021-09- 30	Healthcare Professional	Non EEA	18-64 Years	Female	Contusion (n/a - Fatal - Results in Death), Haemorrhage (n/a - Fatal - Results in Death), Haemorrhagic adrenal infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - Results in Death), Rash (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
711	click or scan EU-EC- 10010186836			Healthcare Professional	Non EEA	18-64 Years	Male	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S-COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
712	EU-EC- 10010186690			Healthcare Professional	Non EEA	65-85 Years	Female	Malaise (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
713	EU-EC- 10010186412			Healthcare Professional	EEA	18-64 Years	Male	Myocardial ischaemia (n/a - Fatal - <u>Results in Death</u> , Life Threatening)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
714	EU-EC- 10010186267		2021-09- 30	Healthcare Professional		65-85 Years	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Drug ineffective (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
715	EU-EC- 10010186130		2021-09- 30	Healthcare Professional	Non EEA	More than 85 Years	Female	Apnoea (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
716	elick or scan EU-EC- 10010185826		2021-09-	Healthcare Professional	EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])

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#	EU Local Number		Gateway Receipt Date		Primary Source Country for Regulatory Purposes	Croup	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
717	elick or scan EU-EC- 10010185010	国際教養の教養を	2021-09- 30	Healthcare Professional	Non EEA	65-85 Years	Female	Dizziness (n/a - Fatal - Results in Death, Other Medically Important Condition), Headache (n/a - Fatal - Results in Death, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - Results in Death, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
718	EU-EC- 10010185001		2021-09- 30	Healthcare Professional	Non EEA	65-85 Years	Male	Adverse event following immunisation (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
719			2021-09-	Healthcare Professional	Non EEA	More than 85 Years	Male	Aortic valve incompetence (n/a - Fatal - Results in Death, Disabling, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Cholecystitis acute (n/a - Fatal - Results in Death, Other Medically Important Condition), Cholelithiasis (n/a - Unknown -), Callbladder hypofunction (n/a - Unknown - Other Medically Important Condition), Heart rate increased (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Oral candidiasis (n/a - Unknown -), Pleural effusion (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved -), Rash (790min - Recovered/Resolved -), Renal disorder (n/a - Unknown -), Sepsis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
720	EU-EC- 10010183112	歌樂	2021-09- 30	Healthcare Professional	EEA	65-85 Years	Male	Foreign body in respiratory tract (n/a - Fatal - Results in Death), Giant cell arteritis (n/a - Fatal - Results in Death), Lymphocytic infiltration (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a])
721	EU-EC- 10010183023			Healthcare Professional	Non EEA	18-64 Years	Male	Leukaemia (0d - Fatal - Results in Death, Other Medically Important Condition), Peripheral circulatory failure (0d - Fatal - Results in Death)	n/a]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
722	EU-EC- 10010182745		2021-09- 30	Non Healthcare Professional	Non EEA	Not Specified	Male	Myocardial infarction (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
723	EU-EC- 10010182743		2021-09- 30	Healthcare Professional	Non EEA	65-85 Years		Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
724	click or scan EU-EC- 10010182709		2021-09- 30	Healthcare Professional	Non EEA	65-85 Years	Female	COVID-19 (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
725	click or scan EU-EC- 10010181500		2021-09- 30	Healthcare Professional	EEA	18-64 Years	Male	Diarrhoea (n/a - Fatal - <u>Results in Death</u>), Vomiting (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
726	elick or scan EU-EC- 10010181479		2021-09- 30	Non Healthcare Professional	EEA	65-85 Years	Female	Plasmacytoma (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
72	EU-EC- 10010181467		2021-09- 30	Healthcare Professional	EEA	18-64 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
72	EU-EC- 10010181462		2021-09- 30	Healthcare Professional	EEA	18-64 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
72	click or scan EU-EC- 10010181461		2021-09- 30	Non Healthcare Professional	EEA	65-85 Years	Male	Cardiac failure acute (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Cardiac valve vegetation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary fibrosis (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
73	EU-EC- 10010181367		2021-09- 30	Healthcare Professional	Non EEA	More than 85 Years	Male	Lacunar infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
73	EU-EC- 10010181361		2021-09- 30	Non Healthcare Professional	Non EEA	18-64 Years	Female	Chills (n/a - Fatal - <u>Results in Death</u>), Pyrexia (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
73	EU-EC- 10010181261		2021-09- 30	Healthcare Professional	Non EEA	More than 85 Years		COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
73	EU-EC- 10010181139		2021-09- 30	Healthcare Professional	Non EEA	18-64 Years	Male	Acute myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
73	click or scan EU-EC- 10010180914		2021-09- 30	Non Healthcare Professional	EEA	65-85 Years	Male	Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Device occlusion (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Enteritis (5d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hospitalisation (5d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - Results in Death), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Preumonia (n/a - Unknown - Life Threatening)	MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a])
73	click or scan EU-EC- 10010180383		2021-09- 30	Healthcare Professional	Non EEA	65-85 Years		Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Hepatic function abnormal (29d - Recovered/Resolved -), Interstitial lung disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malignant pleural effusion (n/a - Unknown - Other Medically Important Condition), Pneumothorax (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - Results in Death), Stress cardiomyopathy (n/a - Unknown - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mg - Intramuscular], [ABEMACICLIB] (S - Breast cancer recurrent - Drug withdrawn - [21d - 200mg - Oral - More in ICSR]), [ANASTROZOLE] (S - Breast cancer recurrent - Drug withdrawn - [42d - 1mg - Oral - More in ICSR])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
736	EU-EC- 10010180275	国際経済を持ち	2021-09- 30	Healthcare Professional	Non EEA	18-64 Years	Male	Cardiovascular insufficiency (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
737	EU-EC- 10010180048		2021-09- 30	Healthcare Professional	EEA	65-85 Years	Male	COVID-19 pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular])
738	EU-EC- 10010180018		2021-09- 30	Healthcare Professional	EEA	More than 85 Years	Male	Vaccination failure (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Cutaneous])
739	EU-EC- 10010179943		2021-09- 30	Healthcare Professional	EEA	65-85 Years	Male	Myocardial infarction (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])
740	10010179656		2021-09- 30	Healthcare Professional	Non EEA	18-64 Years		Cardiogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Encephalitis autoimmune (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Postictal state (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
741	EU-EC- 10010179403		2021-09- 30	Healthcare Professional	Non EEA	18-64 Years	Male	Completed suicide (n/a - Fatal - Results in Death), Depression (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
742	EU-EC- 10010179352		2021-09- 30	Healthcare Professional	Non EEA	65-85 Years	Male	Arterial occlusive disease (n/a - Fatal - Results in Death , Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - Results in Death , Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
743	EU-EC- 10010179221	1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	2021-09- 30	Healthcare Professional	EEA	65-85 Years	Male	Body temperature increased (1d - Recovered/Resolved -), Fatigue (1d - Recovering/Resolving -), Gait disturbance (1d - Recovered/Resolved -), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [HALOPERIDOL] (S - n/a - n/a - [n/a - n/a - n/a])
744	elick or scan EU-EC- 10010179117			Healthcare Professional	Non EEA	65-85 Years	Female	Abdominal distension (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Abdominal pain (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Anal incontinence (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Castrointestinal injury (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Refusal of treatment by patient (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination complication (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
745	<u>click or scan</u> EU-EC- 10010179014		2021-09- 30	Non Healthcare Professional	EEA	More than 85 Years	Female	Contusion (44d - Fatal - Results in Death, Other Medically Important Condition), Movement disorder (12d - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (12d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])

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#	EU Local Number	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
746	<u>click or scan</u> EU-EC- 10010178938	2021-09- 30	Healthcare Professional	Non EEA	Not Specified	Male	Aortic aneurysm rupture (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])
747	EU-EC- 10010178669	2021-09- 30	Non Healthcare Professional	EEA	65-85 Years	Female	Arrhythmia (n/a - Unknown -), Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
748	<u>click or scan</u> EU-EC- 10010178614	2021-09-	Healthcare Professional	Non EEA	65-85 Years	Female	Arrhythmia (n/a - Unknown -), Death (n/a - Fatal - Results in Death). Arrhythmia (n/a - Unknown -), Death (n/a - Fatal - Results in Death) COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ecrebral infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Earlian intolerance (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cher Medically Important Condition) Stdken death (0d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation) Ceneral physical health deterioration (5d - Fatal - Results in Death), Myalgia (5d - Fatal - Results in Death), Nausea (5d - Fatal - Results in Death), Caused/Prolonged Hospitalisation) Cytomegalovirus infection (n/a - Unknown - Other Medically Important Condition), Thrombotic microangiopathy (n/a - Fatal - Results in Death), Caused/Prolonged Hospitalisation, CoVID-19 (25d - Fatal - Results in Death), Caused/Prolonged Hospitalisation, CoVID-19 pneumonia (23d - Fatal - Results in Death), Caused/Prolonged Hospitalisation, CoVID-19 pneumonia (23d - Fatal - Results in Death), Caused/Prolonged Hospitalisation, CoVID-19 pneumonia (23d - Fatal - Results in Death), Caused/Prolonged Hospitalisation, CoVID-19 pneumonia (23d - Fatal - Results in Death), Caused/Prolonged Hospitalisation, CoVID-19 pneumonia (23d - Fatal - Results in Death), Caused/Prolonged Hospitalisation, CoVID-19 (25d - Fatal - Results in Death), Caused/Prolonged H	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
749	<u>click or scan</u> EU-EC- 10010177798	2021-09- 30	Healthcare Professional	EEA	18-64 Years	Male	Sudden death (0d - Fatal - <u>Results in Death</u> , Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])
750	EU-EC- 10010177519		Healthcare Professional	EEA	65-85 Years	Male	General physical health deterioration (5d - Fatal - <u>Results in Death</u>), Myalgia (5d - Fatal - <u>Results in Death</u>), Nausea (5d-Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
751	EU-EC- 10010177035	2021-09- 30	Healthcare Professional	EEA	18-64 Years	Female	Cytomegalovirus infection (n/a - Unknown - Other Medically Important Condition), Thrombotic microangiopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]), TACROLIMUS [TACROLIMUS, TACROLIMUS MONOHYDRATE] (S - Product used for unknown indication - Drug withdrawn - [172d - n/a - Unknown])
752	EU-EC- 10010176649	2021-09- 30	Healthcare Professional	Non EEA	More than 85 Years	Female	Acute respiratory failure (23d - Fatal - Results in Death, Other Medically Important Condition), Ageusia (n/a - Unknown -), COVID-19 (25d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (23d - Fatal - Results in Death, Other Medically Important Condition), Castroenteritis viral (23d - Fatal - Results in Death), Inappropriate schedule of product administration (1d - Recovered/Resolved -), Vaccination failure (n/a - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
753	EU-EC- 10010176555		Healthcare Professional	Non EEA	18-64 Years	Male	Pulmonary embolism (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
754	click or scan EU-EC- 10010176409	2021-09-	Non Healthcare Professional	EEA	18-64 Years		Malaise (6d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])

#	EU Local Number	EV Gateway Receipt Date	Primary Source Qualification	for	Age	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
755	EU-EC- 10010176395	2021-09- 30	Non Healthcare Professional	EEA	18-64 Years	Male	Sudden cardiac death (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a])
756	EU-EC- 10010175952	2021-09- 30	Healthcare Professional	Non EEA	65-85 Years	Male	Cardiac failure congestive (1d - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
757	click or scan EU-EC-	2021-09- 30	Non Healthcare Professional	EEA	18-64 Years	Female	Arterial thrombosis (n/a - Fatal - Results in Death), Cerebrovascular accident (n/a - Fatal - Results in Death), Embolism arterial (n/a - Fatal - Results in Death), Castrointestinal haemorrhage (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26,COV2.S) - SUSPENSION FOR INJECTION (S - n/a - n/a - [n/a - n/a - Intramuscular])
758	click or scan	2021-09- 30	Healthcare Professional	Non EEA	More than 85 Years	Male	Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood creatine phosphokinase MB increased (n/a - Unknown - Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - Results in Death, Other Medically Important Condition), Chest discomfort (n/a - Unknown -), Coronary artery stenosis (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown -), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Oedema peripheral (n/a - Unknown -), Pallor (n/a - Unknown -), Ventricular fibrillation (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
759	EU-EC- 10010175529	2021-09- 30	Healthcare Professional		65-85 Years	Female	Death (0d - Fatal - <u>Results in Death</u>), Hemiplegia (4d - Fatal - <u>Results in Death</u>), Ischaemic stroke (4d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
760	click or scan EU-EC- 10010175327	2021-09-	Healthcare Professional	Non EEA	65-85 Years	Female	Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
761	EU-EC- 10010175062	2021-09- 30	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
762	click or scan EU-EC- 10010174998	2021-09- 30	Healthcare Professional	Non EEA	18-64 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
763	click or scan EU-EC- 10010174995	30	Non Healthcare Professional	EEA	18-64 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>), Fatigue (10d - Unknown -), Headache (10d - Unknown -), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Unknown -), Polymerase chain reaction positive (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (10d - Unknown -)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])

#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
764	EU-EC- 10010174642		2021-09- 30	Healthcare Professional	Non EEA	18-64 Years	Female	Abdominal pain (n/a - Fatal - Results in Death), Asthenia (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pruritus (n/a - Fatal - Results in Death), Pruritus (n/a - Fatal - Results in Death), Pruritus (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
765	click or scan EU-EC- 10010174442		2021-09- 30	Healthcare Professional	EEA	18-64 Years		Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation)	OPDIVO [NIVOLUMAB] (S - Lung adenocarcinoma - Not applicable - [n/a - 240mg - Intravenous (not otherwise specified)]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
766	click or scan EU-EC- 10010173712		2021-09- 30	Healthcare Professional	Non EEA	65-85 Years	Female	Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) OPDIVO [NIVOLUMAB] (S - Lung adenocarcinoma - Not applicable - [n/a - 240mg - Intravenous (not otherwise specified)]), \$PIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Oral]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])
767	EU-EC- 10010172952		2021-09- 30	Non Healthcare Professional	EEA	More than 85 Years	Female	Agitation (35d - Fatal - Results in Death), Confusional state (35d - Fatal - Results in Death), Nervous system disorder (35d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Oral])
768	elick or scan EU-EC- 10010172894		2021-09- 30	Non Healthcare Professional	EEA	65-85 Years	Male	Bradycardia (5d - Fatal - Results in Death), Confusional state (5d - Fatal - Results in Death), Melaena (5d - Fatal - Results in Death), Renal failure (5d - Fatal - Results in Death), Swelling face (5d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])
769	EU-EC- 10010170630		2021-09- 30	Healthcare Professional	EEA	65-85 Years	Male	Pneumonitis (24d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
770	EU-EC- 10010171930		2021-09- 29	Non Healthcare Professional	EEA	65-85 Years	Male	Respiratory disorder (n/a - Fatal - Results in Death, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])
771	click or scan EU-EC-		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Male	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (2d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
772	click or scan		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Male	Diarrhoea (n/a - Fatal - <u>Results in Death</u>), Malnutrition (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])

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		EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
,	773	<u>click or scan</u> EU-EC- 10010171264		2021-09- 29	Healthcare Professional	EEA	More than 85 Years	Female	Dyspnoca (1d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])
	774	<u>click or scan</u> EU-EC- 10010170909		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Male	Angiogram abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Certral pain syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computerised tomogram neck (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diath (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diath (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diath (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Electroencephalogram (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bradotracheal intulation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Paranasal sinus discomfort (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Perfusion brain scan (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Perfusion brain scan (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Perfusion brain scan (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Posterior fossa syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Perfusion brain Scan (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Perfusion brain Scan (n/a -	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-
,	775	<u>click or scan</u> EU-EC- 10010170878		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	Acute hepatic failure (n/a - Fatal - Results in Death), Acute left ventricular failure (n/a - Fatal - Results in Death), Brain herniation (n/a - Fatal - Results in Death), Brain herniation (n/a - Fatal - Results in Death), Brain noedema (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Computerised tomogram head abnormal (n/a - Fatal - Results in Death), Distributive shock (n/a - Fatal - Results in Death), Echocardiagram abnormal (n/a - Fatal - Results in Death), Endotracheal intubation (n/a - Fatal - Results in Death), Gastrointestinal haemorrhage (n/a - Fatal - Results in Death), Haematemesis (n/a - Fatal - Results in Death), Hyperammonaemia (n/a - Fatal - Results in Death), Hyperventilation (n/a - Fatal - Results in Death), Intracranial pressure increased (n/a - Fatal - Results in Death), Laboratory test (n/a - Fatal - Results in Death), Latora caidosis (n/a - Fatal - Results in Death), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pupil fixed (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S- Immunisation - Not applicable - [n/a - n/a - Intramuscular])
,	776	<u>click or scan</u> EU-EC- 10010170846		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	r1.	COVID-19 (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung infiltration (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary oedema (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
,	777	<u>click or scan</u> EU-EC- 10010170770			Healthcare Professional	Non EEA	18-64 Years		Arteriosclerosis (n/a - Fatal - Results in Death), Autopsy (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])
,	778	<u>click or scan</u> EU-EC- 10010169940		2021-09-	Healthcare Professional	Non EEA	65-85 Years		COVID-19 (n/a - Fatal - <u>Results in Death</u> , Other Medically Important Condition), Vaccination failure (n/a - Unknown - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])

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		EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
7	79	click or scan EU-EC- 10010169869		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Female	Sudden cardiac death (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])
7	80	click or scan EU-EC- 10010169790		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	Abdominal pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Activated partial thromboplastin time shortened (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Blood fibrinogen decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Blood fibrinogen decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Crebral haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Haemoglobin normal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Haemostasis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Haemostasis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Haemostasis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Heaparin-induced thrombocytopenia test positive (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intrarcanial pressure increased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prothrombin time prolong	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
7	81	click or scan EU-EC- 10010169444		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Male	Chest pain (n/a - Fatal - <u>Results in Death</u>), Loss of consciousness (n/a - Fatal - <u>Results in Death</u>), Myoclonus (n/a - Fatal - <u>Results in Death</u>), Ventricular tachycardia (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
7	82	click or scan EU-EC- 10010169434		2021-09- 29	Non Healthcare Professional	Non EEA	Not Specified	Molo	Death (n/a - Fatal - <u>Results in Death</u> , Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
7	83	click or scan		2021-09- 29	Healthcare Professional	EEA	18-64 Years	Male	Mechanical ventilation (n/a - Fatal - <u>Results in Death</u>), Somnolence (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])
7	84	click or scan		2021-09- 29	Healthcare Professional	EEA	Not Specified	Female	Death (n/a - Fatal - <u>Results in Death</u>), Illness (n/a - Unknown - <u>Results in Death</u>)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown])

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#	EU Local Number		Gateway	O1:6:4:	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
785	<u>click or scan</u> EU-EC- 10010168842		2021-09- 29	Healthcare Professional	EEA	65-85 Years	Male	Death (0d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
786	<u>click or scan</u> EU-EC- 10010168834	EDITOR PROPERTY	2021-09- 29	Non Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (n/a - Fatal - <u>Results in Death</u>), Drug ineffective (n/a - Fatal - <u>Results in Death</u>)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
787	EU-EC- 10010168775	E1000 MOVE 450	29	Healthcare Professional	Non EEA	65-85 Years	Male	Death (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	immunisation - Not applicable - [n/a3mL - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular])
788	<u>click or scan</u> EU-EC- 10010168594		2021-09- 29	Healthcare Professional	EEA	65-85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
789	<u>click or scan</u> EU-EC- 10010168586		2021-09- 29	Healthcare Professional	EEA	More than 85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
790	EU-EC- 10010168584		2021-09-	Healthcare Professional	EEA	More than 85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
791	<u>click or scan</u> EU-EC- 10010168557		2021-09- 29	Healthcare Professional	EEA	18-64 Years	Male	Chest discomfort (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular])
792	<u>click or scan</u> EU-EC- 10010168439		2021-09- 29	Healthcare Professional	EEA	More than 85 Years	Male	Vaccination failure (20d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])
793	EU-EC- 10010168438		2021-09- 29	Healthcare Professional	EEA	18-64 Years	Male	Vaccination failure (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2{DF} - Intramuscular])
794	<u>click or scan</u> EU-EC- 10010168413		29	Healthcare Professional	EEA	65-85 Years	Male	Death (29d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
795	click or scan EU-EC- 10010168401		2021-09- 29	Healthcare Professional	EEA	More than 85 Years	Male	Pulmonary embolism (5d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
796	EU-EC- 10010168397		2021-09- 29	Healthcare Professional	EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
797	EU-EC- 10010168394		2021-09- 29	Healthcare Professional	EEA	65-85 Years	Male	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
798	EU-EC- 10010168258		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Female	Arteriosclerosis coronary artery (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonitis (n/a - Fatal - Results in Death), Supraventricular tachycardia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
799	EU-EC- 10010168256		29	Healthcare Professional	Non EEA	Not Specified	Not Specified	Foetal heart rate abnormal (n/a - Fatal - <u>Results in Death</u>), Maternal exposure before pregnancy (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])
800	click or scan EU-EC- 10010168190		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Female	Thrombocytopenia (n/a - Fatal - <u>Results in Death</u>), Thrombosis (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [1d - n/a - Intramuscular])
801	click or scan			Healthcare Professional	Non EEA	65-85 Years	Male	Ageusia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anosmia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Catheter site haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Device related infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Recovered/Resolved -), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Suphylococcal bacteraemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
802	EU-EC- 10010167783		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Male	Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interstitial lung disease (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Organising pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
803	EU-EC- 10010167501		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
804	click or scan EU-EC- 10010166898		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])

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#	EU Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
805	EU-EC- 10010166577		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Embolism (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
806	EU-EC- 10010166368		2021-09- 29	Non Healthcare Professional	EEA	65-85 Years	Female	Headache (43d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])
807	click or scan EU-EC- 10010166146		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Female	Acute respiratory failure (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Could Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved -)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - 1 {TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - 1 {TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - 1 {TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - 1 {TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])
808	EU-EC- 10010165375		2021-09- 29	Healthcare Professional	EEA	18-64 Years	Male	Cardiac arrest (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (24d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Immobile (24d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])
809	EU-EC- 10010165348		2021-09- 29	Healthcare Professional	EEA	65-85 Years	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - In/a - In/a - n/a - Intramuscular])
810	EU-EC- 10010165301		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
811	click or scan EU-EC- 10010165206		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebrovascular accident (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic kidney disease (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
812	click or scan EU-EC- 10010165076		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	COVID-19 (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])
813	<u>click or scan</u> EU-EC- 10010165074		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Female	Sudden cardiac death (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])
814	EU-EC- 10010164890		2021-09- 29	Non Healthcare Professional	EEA	65-85 Years	Male	Pneumonia (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])

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#	EU Local Number	ICSK FORM	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes		Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
815	EU-EC- 10010164683		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (14d - Fatal - <u>Results in Death</u>), Exposure to SARS-CoV-2 (14d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
816			29	Healthcare Professional	Non EEA	More than 85 Years	Not Specified	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
817	10010164540			Healthcare Professional	EEA	18-64 Years	Female	Administration site pain (2d - Recovered/Resolved -), Brain oedema (n/a - Fatal - Results in Death), Cerebral haemorrhage (n/a - Fatal - Results in Death), Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Paresis (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death), Vomiting (n/a - Unknown - Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
818	EU-EC- 10010164332		2021-09- 29	Non Healthcare Professional	Non EEA	Not Specified	Male	Cardiac failure congestive (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
819	EU-EC- 10010164103		29	Healthcare Professional	EEA	65-85 Years	Female	Death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])
820	EU-EC- 10010164092		2021-09- 29	Healthcare Professional	EEA	65-85 Years	Female	Abdominal pain upper (n/a - Fatal - <u>Results in Death</u>), Bradycardia (n/a - Fatal - <u>Results in Death</u>), Dyspnoea (n/a - Fatal - <u>Results in Death</u>), Ventricular fibrillation (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a3mL - Intramuscular])
821	EU-EC- 10010163874		2021-09-	Healthcare Professional	Non EEA	65-85 Years	Male	Asthenia (17d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (17d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (17d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (17d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
822	EU-EC- 10010163390		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Male	Fall (39d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (39d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Head injury (39d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intracranial mass (39d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (39d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metastases to meninges (39d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
823	elick or sean EU-EC- 10010163200		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])

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#	EU Local Number	ICSR Form	Gateway Possint	Qualification	Country	Age	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
824				Healthcare Professional	EEA	18-64 Years	Female	Altered state of consciousness (n/a - Fatal - Results in Death), Arteriosclerosis (n/a - Fatal - Results in Death), Asthenia (n/a - Fatal - Results in Death), Cardiac steatosis (n/a - Fatal - Results in Death), Cholelithiasis (n/a - Fatal - Results in Death), Haemorrhagic infarction (n/a - Fatal - Results in Death), Hepatic steatosis (n/a - Fatal - Results in Death), Invasive ductal breast carcinoma (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Myocardial fibrosis (n/a - Fatal - Results in Death), Phulmonary congestion (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Results in Death), Results in Death), Results in Death), Somnolence (n/a - Fatal - Results in Death), Speech disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-02414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
825	elick or scan EU-EC- 10010162780		2021-09- 29	Healthcare Professional	EEA	18-64 Years	Male	Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
826	<u>click or scan</u> EU-EC- 10010162505		2021-09- 29	Non Healthcare Professional	Non EEA	18-64 Years	Female	COVID-19 (n/a - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown])
827	EU-EC- 10010162503		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years		Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
828	click or scan			Healthcare Professional	Non EEA	65-85 Years	iviale	Benign prostatic hyperplasia (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diabetes mellitus (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
829	EU-EC- 10010162461			Healthcare Professional	Non EEA	18-64 Years	Female	Congestive cardiomyopathy (1d - Fatal - Results in Death, Other Medically Important Condition), Sudden death (1d - Fatal - Results in Death, Other Medically Important Condition), Vaccination site pain (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
830	EU-EC- 10010162431	野女祖 新典者		Healthcare Professional	EEA	65-85 Years	Male	Acute myocardial infarction (1d - Fatal - Results in Death), Angina pectoris (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a])
831	<u>click or scan</u> EU-EC- 10010162428		29	Healthcare Professional	EEA	65-85 Years	Female	Acute myocardial infarction (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a])
832	click or scan EU-EC- 10010162327		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Female	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Injection site pruritus (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
833	click or scan		2021-09-	Healthcare Professional	Non EEA	More than 85 Years	Female	Asthenia (n/a - Fatal - <u>Results in Death</u>), Fatigue (n/a - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])

# I	EU Local Number	ICSR Form	EV Gateway	I	Primary Source				
			Receipt Date	Source Qualification	Country	Age	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
834	<u>click or scan</u> EU-EC- 10010162299			Healthcare Professional	Non EEA	65-85 Years	Male	Sudden cardiac death (n/a - Fatal - <u>Results in Death</u>)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])
835	<u>click or scan</u> EU-EC- 10010162167			Healthcare Professional	Non EEA	65-85 Years	Male	Asthenia (144d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) COVID-19 MRNA VACCINE MODERNA (CX-
836	EU-EC- 10010162130		29	Healthcare Professional	Non EEA	65-85 Years	Male	Death (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
837	elick or scan EU-EC- 10010162124		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory syncytial virus infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
	click or scan			Healthcare Professional	EEA	18-64 Years	Male	Acne (n/a - Fatal - Results in Death), Acute myocardial infarction (n/a - Fatal - Results in Death), Altered state of consciousness (n/a - Fatal - Results in Death), Brain herniation (n/a - Fatal - Results in Death), Brain oedema (n/a - Fatal - Results in Death), Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death), Other Medically Important Condition), Cerebral infarction (n/a - Fatal - Results in Death), Creebral venous sinus thrombosis (n/a - Fatal - Results in Death), Disseminated intravascular coagulation (n/a - Fatal - Results in Death), Castrointestinal necrosis (n/a - Fatal - Results in Death), Disseminated intravascular coagulation (n/a - Fatal - Results in Death), Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death), Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death), Other Medically Important Condition), Patal - Results in Death), Other Medically Important Condition), Patal - Results in Death), Other Medically Important Condition), Patal - Results in Death), Venous pressure increased (n/a - Fatal - Results in Death), Venous pressure increased (n/a - Fatal - Results in Death), Visual field defect (n/a - Fatal - Results in Death)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular])
839	elick or scan EU-EC- 10010162062		29	Healthcare Professional	Non EEA	18-64 Years	Male	COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-
840	<u>click or scan</u> EU-EC- 10010161992		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years		Decreased appetite (8d - Fatal - <u>Results in Death</u>), Feeling abnormal (8d - Fatal - <u>Results in Death</u>), Gait inability (8d - Fatal - <u>Results in Death</u>)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
841	elick or scan EU-EC- 10010161853		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Male	Unresponsive to stimuli (1d - Fatal - <u>Results in Death</u> , Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])
842	<u>click or scan</u> EU-EC- 10010161839		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Male	COVID-19 (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoca (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
843	click or scan			Healthcare Professional	Non EEA	18-64 Years	Male	Heparin-induced thrombocytopenia (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])

Manual "ICSR Form" request: Copy & Paste following Link AND then replace ****** with "EU Local Number" (only digits!) https://dap.ema.europa.eu/xmlpserver/PHV%20DAP/Reports/ICSR.xdo?_xpf=&_xt=form&SR_ID=****** &_xpt=1&_xf=pdf

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		EU Local Number	ICSR Form	EV Gateway Receipt Date		Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT(Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route])
	44			2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Male	Cerebrovascular accident (n/a - Fatal - <u>Results in Death</u>), Death (n/a - Fatal - <u>Results in Death</u>), Thrombosis (n/a - Fatal - <u>Results in Death</u>)	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular])
8	45	click or scan EU-EC- 10010161625		2021-09- 29	Healthcare Professional	EEA	65-85 Years	Male	Asthenia (9d - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])
8	46	elick or scan EU-EC- 10010161615		2021-09- 29	Non Healthcare Professional	EEA	65-85 Years	Not Specified	Cardiogenic shock (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a])
1	47	click or scan EU-EC- 10010161523		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Male	Acidosis (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthenia (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bradycardia (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death), Dyspnoea (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigue (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigue (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigue (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigue (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigue (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigue (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigues (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Patigues (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Patiguess electrical activity (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Sinus tachycardia (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ventricular tachycardia (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ventricular tachycardia (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ventricular tachycardia (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ventricular tachycardia (23d - Fatal - Results in Death,	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]) SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
8	48	click or scan EU-EC- 10010161332		2021-09- 29	Non Healthcare Professional	Non EEA	65-85 Years	Male	Amnesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Balance disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epilepsy (78d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cait inability (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urinary incontinence (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])
1	49	EU-EC-		2021-09- 29	Non Healthcare Professional	Non EEA	More than 85 Years		Cardiomyopathy (n/a - Fatal - Results in Death , Other Medically Important Condition), Death (n/a - Fatal - Results in Death , Other Medically Important Condition), Lacrimation increased (n/a - Unknown -), Myocarditis (n/a - Fatal - Results in Death , Other Medically Important Condition), Paraesthesia (n/a - Unknown -), Peripheral swelling (n/a - Unknown -), Pruritus (n/a - Unknown -), Skin (n/a - Unknown -), Skin exfoliation (n/a - Unknown -), Skin exfoliation (n/a - Unknown -), Swelling face (n/a - Unknown -)	(CX-024414)] (S- COVID-19 immunisation - Not
1	50	EU-EC-10010161297		2021-09- 29	Healthcare Professional	Non EEA	More than 85 Years	Female	Condition aggravated (72d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dysgeusia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (72d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Muscular weakness (72d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (72d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown])

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;		U Local Number	ICSR Form	EV Gateway Receipt Date	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Patient Age Group	Patient Sex	Reaction List PT (Duration - Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
8:	51	EU-EC- 0010161110		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years		Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - Results in Death., Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (3d - Recovered/Resolved -), Pneumonia aspiration (3d - Fatal - Results in Death., Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR])
8:	52	EU-EC- 0010161019		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Male	Cardiac arrest (n/a - Fatal - <u>Results in Death</u>), Malaise (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
8:	53			2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Female	Acute respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Asthenia (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown -), Pneumonia (8d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR])
8:	54	click or scan		2021-09- 29	Non Healthcare Professional	Non EEA	18-64 Years	Male	Arteriosclerosis coronary artery (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Chest pain (n/a - Fatal - Results in Death), Cyanosis (15d - Fatal - Results in Death), Fatigue (15d - Fatal - Results in Death), Headache (15d - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death), Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - Results in Death), Peripheral swelling (15d - Fatal - Results in Death)	(CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOXI NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
8:	55	EU-EC- 0010160841		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])
8:	56	EU-EC- 0010160728		2021-09- 29	Healthcare Professional	Non EEA	18-64 Years	Male	Adverse event following immunisation (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
8:	57	EU-EC- 0010160711		2021-09- 29	Healthcare Professional	Non EEA	65-85 Years	Male	Cerebrovascular accident (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])
8:	58			2021-09- 29	Non Healthcare Professional	EEA	65-85 Years	Male	Sudden death (n/a - Fatal - <u>Results in Death</u>)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
8:	59	EU-EC- 0010160299		2021-09- 29	Non Healthcare Professional	EEA	18-64 Years	Male	Migraine (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])
80	60	FLLEC		2021-09- 29	Non Healthcare Professional	EEA	65-85 Years		Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular])