From: Execdiva [EMAIL ADDRESS REDACTED]
Sent: Saturday, January 22, 2022 11:58 AM
To: SNHD Public Comments
Subject: Fwd: Public Comment Meeting Jan 27th 2022
Attachments: Pfizer Nov 23rd release of trial data thousands of adverse events as of Feb 21.pdf; 3100 plus COVID Vaccine Calims on HRSA zero compensation.pdf; Moderna-fact-sheet-pi-providers-booster-Final_0.pdf; PfizerListofAdverseEvents.pdf; SNHD Leguen complaint.pdf

I have filed a complaint with the Nevada Attorney General regarding Fermin Leguen falsifying/not reporting reports to the public which is against Nevada Law

Non disclosure of vaccine deaths and injury (Sentinel Events-259 reported in Nevada) in reporting from all sources, medical, VAERS and attached court ordered report publicly available since 11/23/2021 from Pfizer post marketing experience

Not enforcing full disclosure to vaccine recipients of data fact sheets and potential adverse events

Elizabeth Hammack,

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

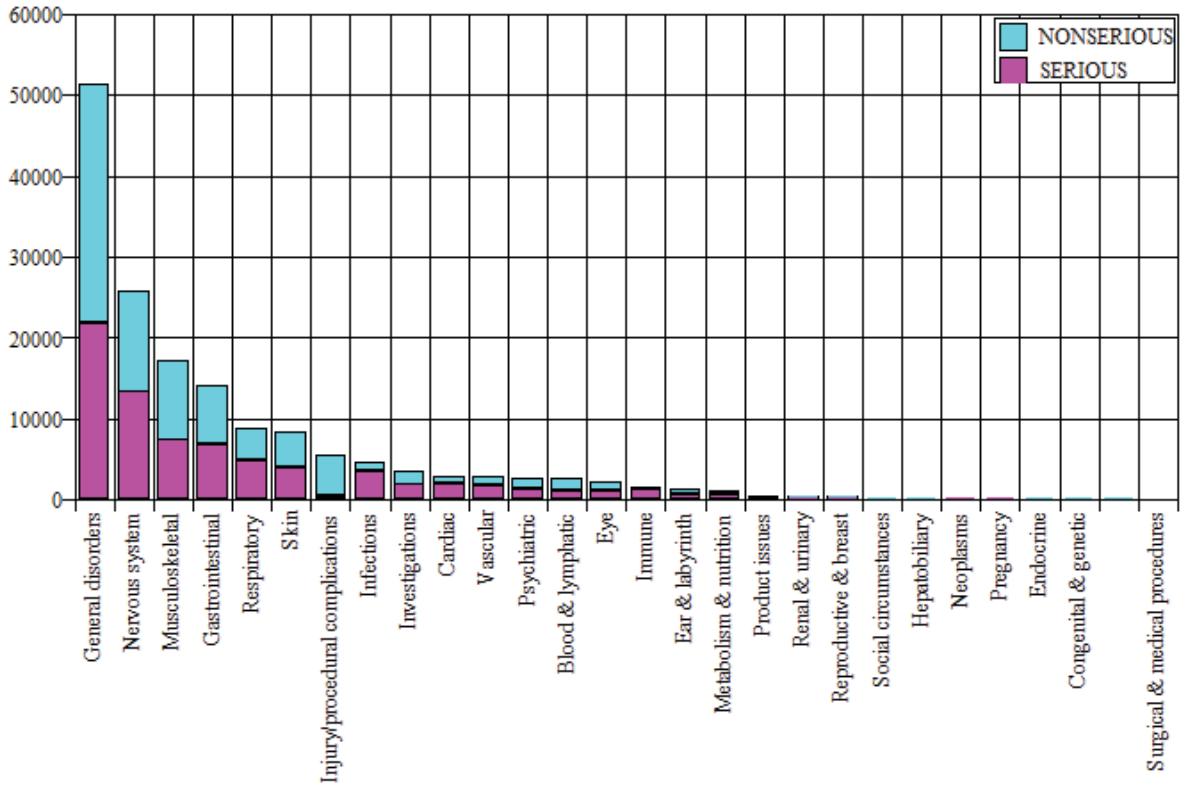

Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.
Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy: The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below: • PT "Vaccination failure" is coded when ALL of the following criteria are met: o The subject has received the series of two doses per the dosing regimen in local labeling. o At least 7 days have elapsed since the second dose of vaccine has been administered. o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19". o It is unknown: ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling; ▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.); ▪ If 7 days have passed since the second dose; o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete. Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

  Medication error case outcomes:

  - Fatal (7)[3],
  - Recovered/recovering (354, of which 4 are serious),
  - Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

Countermeasures Injury Compensation Program (CICP) Data

Aggregate Data as of October 1, 2021

The Countermeasures Injury Compensation Program (CICP) provides compensation for covered serious injuries or deaths that, based on compelling, reliable, valid, medical and scientific evidence, are found to be directly caused by the administration or use of a covered countermeasure or are determined to meet the requirements of a countermeasure injury table. Temporal association between administration or use of the covered countermeasure and onset of the injury (i.e., the injury occurs a certain time after the administration or use) is not sufficient, by itself, to prove that an injury is the direct result of a covered countermeasure.

It is important to note that the CICP data only captures the alleged countermeasure(s) and the alleged injuries that CICP requesters list on their Request for Benefits forms (RFB) or claim. The countermeasure or injury listed by the requester on the RFB may or may not be consistent with the requester's medical documentation or the injury resulting in compensation. While requesters are required to identify the alleged countermeasure on their RFB form, they are not required to list the specific manufacturer or trade name on their RFB form.

Furthermore, while requesters must submit their RFB form within 1 year from the administration or use of the covered countermeasure, requesters are permitted to submit the necessary medical records and other documentation, such as a copy of a requester's COVID-19 vaccination record, after the RFB is filed. For the majority of COVID-19 countermeasure claims, including COVID-19 vaccine claims, the CICP is still waiting for records and documentation to be submitted.

When was the first CICP claim filed?

The first CICP claim was filed in Fiscal Year (FY) 2010; there are no CICP claims to report on prior to FY 2010.

Is the CICP data available by specific manufacturer or trade name?

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer.

How many claims has the CICP compensated?

The CICP is the payer of last resort and can only reimburse or pay for medical expenses or lost employment income that are not covered by other third-party payers. To date, the CICP has paid compensation for 29 CICP claims, totaling more than $6 million. An additional 10 CICP claims were eligible for compensation after a review of the required medical records and documentation; however, in these cases there were no eligible reported medical expenses or lost employment income for the CICP to compensate.

Has the CICP made any decisions regarding COVID-19 Claims?

As of October 1, 2021, the CICP has not compensated any COVID-19 countermeasures claims. Three COVID-19 countermeasures have been denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. One COVID-19 claim has been determined eligible for compensation and is pending a review of eligible expenses.

CICP Data for Fiscal Years 2010 – 2021 (As of October 1, 2021)

Total CICP Claims Filed: **3,649**

- Claims Eligible for Medical Review: **3,556**
  - Eligible for Compensation: **40**
    - Compensated: **29**
    - No Eligible Reported Expenses: **10**
    - Pending: **1**
  - Pending Review or In Review: **3,154**

- Denied: **362**
  - Requested Medical Records not Submitted: **135**
  - Standard of Proof Not Met and/or Covered Injury not Sustained: **227**
- Claims Ineligible for Medical Review: **93**
  - Missed Filing Deadline: **38**
  - Not CICP Covered Product/ Not Specified: **55**

CICP claims data is provided below in categories pertaining to their status.

Table 1. Alleged COVID-19 Countermeasure Claims Filed as of October 1, 2021

This table displays the alleged countermeasure and alleged injury/death for each COVID-19 countermeasure claim filed as of October 1, 2021. Of the 3,158 COVID-19 countermeasure claims 1,357 allege injuries/deaths from COVID-19 vaccines and 1,801 allege injuries/deaths from other COVID-19 countermeasures.

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer or trade name.

Alleged Countermeasure	Alleged Injury/ Death	Number of Claims
Failure to have infection control programs in place, the failure to have adequate infection control in place, the failure to properly train staff, the failure to provide sufficient staff, the failure to cohort infected and uninfected individuals, the failure to provide PPE to staff and residents, the failure to train on the proper use of PPE, the failure to have adequate procedures in place to deal with infection, the failure to adequately monitor residents for signs of infection, the failure to transfer residents to a higher level of care when needed, the failure to adequately treat residents with COVID, the failure to provide appropriate distancing among residents, the failure to properly report the number of COVID-19 cases and deaths to authorities, and others.	Death	296
Anakinra	Death	1
Antiviral	Death	1
Azithromycin	Death	12
Azithromycin / BiPAP / Ivermectin / Remdesivir	Death	1
Azithromycin / Cefdinir / G-Tube	Death	1
Azithromycin / Cefdinir/ Ibuprofen	Death	1
Azithromycin / Ceftriaxone / Plaquenil	Death	1
Azithromycin / CiPAP	Death	1
Azithromycin / CiPAP / BiPAP	Death	1
Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir	Death	1
Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir / Solu-Medrol	Death	1

Azithromycin / Convalescent Plasma / Hydroxychloroquine / Ivermectin	Death	1
Azithromycin / Dexamethasone / Remdesivir	Death	1
Azithromycin / Dexamethasone / Steroid	Death	1
Azithromycin / Dialysis / Methylprednisolone	Death	1
Azithromycin / Hydroxychloroquine	Death	10
Azithromycin / Hydroxychloroquine / BiPap / Heparin	Death	1
Azithromycin / Hydroxychloroquine / Bolus / Ceftriaxone / Zosyn	Death	1
Azithromycin / Hydroxychloroquine / Dexamethasone	Death	1
Azithromycin / Hydroxychloroquine / Dialysis	Death	1
Azithromycin / Hydroxychloroquine / Dialysis / Solu-Medrol / Tocilizumab	Death	1
Azithromycin / Hydroxychloroquine / Fentanyl / intubation	Death	1
Azithromycin / Hydroxychloroquine / Intubation	Death	5
Azithromycin / Hydroxychloroquine / Methylprednisolone / Tocilizumab	Death	1
Azithromycin / Hydroxychloroquine / Remdesivir	Death	1
Azithromycin / Hydroxychloroquine / Respirator	Death	1
Azithromycin / Hydroxychloroquine / Rocephin	Death	1
Azithromycin / Hydroxychloroquine / Solu-Medrol	Death	1
Azithromycin / Hydroxychloroquine / Solu-Medrol / Steroids	Death	1
Azithromycin / Ivermectin / Methylprednisolone	Death	1
Azithromycin / Ivermectin / Methylprednisolone / Remdesivir	Death	22
Azithromycin / Metoprolol	Death	1
Azithromycin / Ondansetron / Cefdinir	Death	1
Azithromycin / Remdesivir	Death	5
BiPap / Convalescent Plasma / Remdesivir	Death	1
BiPap / COVID-19 Medications / Nebulizer	Death	1
BiPAP / CPAP / COVID-19 Medications	Death	1
BiPAP / High Flow Oxygen / Remdesivir	Death	1
BiPap / Hydroxychloroquine / Doxycycline / Ceftriaxone / Heparin	Death	1
BiPAP / Hydroxychloroquine / Ivermectin	Death	1
BiPAP / Hydroxychloroquine / Ivermectin / Remdesivir	Death	3
BiPap / Hydroxychloroquine / Remdesivir	Death	1
BiPAP / Ivermectin / Remdesivir / Vapotherm	Death	1

Chest Compression / Epinephrine / Intubation	Death	1
Chest Compressions / Epinephrine	Death	1
Contrast	Kidney Injury	1
Convalescent Plasma	Death	4
Convalescent Plasma / Remdesivir	Death	4
Convalescent Plasma / Tocilizumab / Zithromax	Death	1
COVID-19 Antivirals / Antibiotics / Anti-inflammatory Medications / Oxygen Therapy	Death	1
COVID-19 Infection	Death	1
COVID-19 Medications	Death	10
COVID-19 Medications / Intubation	Death	1
COVID-19 Medications / Remdesivir	Death	1
COVID-19 Test	Death	1
COVID-19 Test	Perforated Ethymoidal Artery	1
COVID-19 Test	Punctured Brain / CSF	1
COVID-19 Test / Heparin / Supplemental Oxygen / Ultrasound (Duplex)	Brain Injury / Quadriplegia	1
COVID-19 Test / Oxygen	Death	1
COVID-19 Vaccine	Abdominal Pain	2
COVID-19 Vaccine	Abdominal Pain / Chills / Lightheadedness	1
COVID-19 Vaccine	Abdominal Pain / Diarrhea / Nausea / Vomiting / Bloating	1
COVID-19 Vaccine	Abdominal Pain / Leg Pain	1
COVID-19 Vaccine	Abdominal Pain / Muscle and Joint Pain / Chills / Vision Distortion / Retina Puckering	1
COVID-19 Vaccine	Aches / Dehydration / Vomiting	1
COVID-19 Vaccine	Acute Brain Disorder	1
COVID-19 Vaccine	Acute Congestive Heart Failure / Kidney Damage	1
COVID-19 Vaccine	Acute Hearing Loss	1
COVID-19 Vaccine	Acute Inflammatory Demyelinating Polyneuropathy	1
COVID-19 Vaccine	Acute ITP	1

COVID-19 Vaccine	Acute Kidney Injury	1
COVID-19 Vaccine	Acute Non-traumatic Kidney Injury / Pericardial Effusion / Elevated AST	1
COVID-19 Vaccine	Acute Pancreatitis	1
COVID-19 Vaccine	Acute Renal Failure / Rhabdomyolsis / Myositis	1
COVID-19 Vaccine	Acute Saddle Pulmonary Embolism	1
COVID-19 Vaccine	Addison's Disease Crisis	1
COVID-19 Vaccine	Adhesive Capsulitis	2
COVID-19 Vaccine	Adverse Reaction	2
COVID-19 Vaccine	AIDP / GBS	1
COVID-19 Vaccine	Allergic Reaction	44
COVID-19 Vaccine	Allergic Reaction / Burns on Skin	1
COVID-19 Vaccine	Allergic Reaction / Hypersensitivity	1
COVID-19 Vaccine	Allergic Reaction / Panic Attack	1
COVID-19 Vaccine	Allergic Reaction / Peripheral Neuropathy	1
COVID-19 Vaccine	Allergic Reaction / Tachycardia	1
COVID-19 Vaccine	Alopecia Areata	1
COVID-19 Vaccine	Anaphylactic Reaction	10
COVID-19 Vaccine	Anaphylactic Shock	10
COVID-19 Vaccine	Anaphylactic Shock / Face Swelling / Angioedema	1
COVID-19 Vaccine	Anaphylaxis	22
COVID-19 Vaccine	Anaphylaxis / Vasovagal Syncope / AIDP / AMAN	1
COVID-19 Vaccine	Anemia / Heart Problems / Respiratory Problems / Weakness	1
COVID-19 Vaccine	Anxiety / Lack of Sleep / Agitation	1
COVID-19 Vaccine	Anxiety / Ongoing Confusion	1
COVID-19 Vaccine	Anxiety / Rapid Heartbeat / Depression / Chest Pain /	1

	Headache	
COVID-19 Vaccine	Anxiety / Shortness of Breath / Heart Palpitations	1
COVID-19 Vaccine	Appendicitis	6
COVID-19 Vaccine	Arm and Facial Paralysis / Difficulty Breathing	1
COVID-19 Vaccine	Arm and Hand Numbness / Pain	1
COVID-19 Vaccine	Arm and Leg Tingling / Heartburn / Headache	1
COVID-19 Vaccine	Arm and Neck Injury	1
COVID-19 Vaccine	Arm and Shoulder Injury	6
COVID-19 Vaccine	Arm Injury	15
COVID-19 Vaccine	Arm Injury / Fever	1
COVID-19 Vaccine	Arm Injury / Rotator Cuff Tear	1
COVID-19 Vaccine	Arm Leg and Breast Pain / Swollen Lymph Nodes	1
COVID-19 Vaccine	Arm Numbness / Tingling	1
COVID-19 Vaccine	Arm Numbness and Pain	1
COVID-19 Vaccine	Arm Pain	3
COVID-19 Vaccine	Arm Pain and Numbness / Swollen Lymph Nodes / Loss of Sleep	1
COVID-19 Vaccine	Arm Pit and Chest Swelling	1
COVID-19 Vaccine	Arm Pit and Chest Swelling	1
COVID-19 Vaccine	Arm Pit Swelling	1
COVID-19 Vaccine	Arrhythmia / Stroke / Tachycardia	1
COVID-19 Vaccine	Arrhythmia / Tachycardia	1
COVID-19 Vaccine	Aseptic Meningitis	1
COVID-19 Vaccine	Asthma	1
COVID-19 Vaccine	Asthma Attack / Fatigue	1
COVID-19 Vaccine	Atrial Fibrillation	4
COVID-19 Vaccine	Atrial Flutter	1
COVID-19 Vaccine	Autoimmune Disease	1
COVID-19 Vaccine	AV Block	1

COVID-19 Vaccine	Back Pain / Swollen Lymph Nodes	1
COVID-19 Vaccine	Back Pain and Lumps	1
COVID-19 Vaccine	Bacterial Pneumonia	1
COVID-19 Vaccine	Bell's Palsy	20
COVID-19 Vaccine	Bell's Palsy / Neuropathy	2
COVID-19 Vaccine	Bleeding Ulcers	1
COVID-19 Vaccine	Blood Clot / Brain Bleed	1
COVID-19 Vaccine	Blood Clot / Fluid in Heart and Lungs	1
COVID-19 Vaccine	Blood Clot / Stroke	1
COVID-19 Vaccine	Blood Clots	37
COVID-19 Vaccine	Blood Clots / Collapsed Lung	1
COVID-19 Vaccine	Blood Clots / Heart Murmur	1
COVID-19 Vaccine	Blood Clots / Leg Cramps / Dizziness	1
COVID-19 Vaccine	Blood Clots / Mucus	1
COVID-19 Vaccine	Blood Clots / Nose Bleed	1
COVID-19 Vaccine	Blood Clots / OVA	1
COVID-19 Vaccine	Blood Pressure / Chest Pain / Shortness of Breath	1
COVID-19 Vaccine	Blood Pressure Drop / Low Heart Rate / Vomiting / Fainting / Dizziness	1
COVID-19 Vaccine	Blood Vessel Break in Brain	1
COVID-19 Vaccine	Blurred Vision / Hives / Itching / Tremors	1
COVID-19 Vaccine	Body Aches	1
COVID-19 Vaccine	Bone Pain / Nausea / Trouble Thinking	1
COVID-19 Vaccine	Bowel Obstruction / Swollen Lymph Nodes	1
COVID-19 Vaccine	Brachial Neuritis	2
COVID-19 Vaccine	Brachial Plexopathy	1
COVID-19 Vaccine	Brain Aneurysm	1
COVID-19 Vaccine	Brain Bleed	1

COVID-19 Vaccine	Brain Bleeding / Blood Clots / Pneumonia	1
COVID-19 Vaccine	Brain Hemorrhage	1
COVID-19 Vaccine	Brain Inflammation / Encephalitis	1
COVID-19 Vaccine	Breakdown of Vital Organs	1
COVID-19 Vaccine	Broken Ankle / Concussion	1
COVID-19 Vaccine	Burning Mouth	1
COVID-19 Vaccine	Bursitis	5
COVID-19 Vaccine	Bursitis / Synovitis / Rotator Cuff Tear	1
COVID-19 Vaccine	Bursting Blood Vessels / Constricted Arteries	1
COVID-19 Vaccine	Cardiac Arrhythmia	1
COVID-19 Vaccine	Cardiac Atrial fibrillation	1
COVID-19 Vaccine	Cardiac Issues / Fatigue / Systemic Lupus Erythematosus	1
COVID-19 Vaccine	Cardiogenic Shock / Pericardial Effusion / Atrial Fibrillation	1
COVID-19 Vaccine	Cardiomyopathy	1
COVID-19 Vaccine	Cellulitis	2
COVID-19 Vaccine	Central and Peripheral Demyelinating Syndrome	1
COVID-19 Vaccine	Central Retinal Artery Occlusion	1
COVID-19 Vaccine	Central Retinal Vein Occlusion	1
COVID-19 Vaccine	Central Venous Sinus Thrombosis	3
COVID-19 Vaccine	Central Venus Thrombocytopenia	1
COVID-19 Vaccine	Cephalic Vein Clot	1
COVID-19 Vaccine	Chest Pain / Chest Cavity Inflammation Around Heart	1
COVID-19 Vaccine	Chest Pain / Fever / Headache / Chills	1
COVID-19 Vaccine	Chest Pain / Headache	1

COVID-19 Vaccine	Chest Pain / Joint Pain / Swelling	1
COVID-19 Vaccine	Chest Pain / Low Oxygen / Pneumonia	1
COVID-19 Vaccine	Chest Pain / Rapid Heartbeat	1
COVID-19 Vaccine	Chest Pain / Shortness of Breath	1
COVID-19 Vaccine	Chest Pains	2
COVID-19 Vaccine	Chest Pains / Fever / Chills / Sore Knees / Insomnia / Loss of Appetite	1
COVID-19 Vaccine	Chest Pressure / Rapid Heart Beat	1
COVID-19 Vaccine	Chest Tightness / Shortness of Breath	1
COVID-19 Vaccine	Chest-Neck Pain / Sweating / Blurred Vision / Spike Blood Pressure	1
COVID-19 Vaccine	Chills / Body Ache / Headache	1
COVID-19 Vaccine	Chills / Shaking / Inability to Breathe and Walk	1
COVID-19 Vaccine	Chronic Cough / Headache / Chest Tightness / Chest and Throat Pain	1
COVID-19 Vaccine	Chronic ITP	1
COVID-19 Vaccine	Chronic Lymphocytic Leukemia	1
COVID-19 Vaccine	CIDP	1
COVID-19 Vaccine	Cognitive Loss / Inflammation in Legs / Irregular Heart Rate	1
COVID-19 Vaccine	Cold Sweats / Sore Muscles / Headaches	1
COVID-19 Vaccine	Colitis / Crohn's	1
COVID-19 Vaccine	Coma	1
COVID-19 Vaccine	Concussion	1
COVID-19 Vaccine	Concussion / Fainting	1
COVID-19 Vaccine	Concussion / Seizures / Chipped Teeth / Head and Neck Pain	1

COVID-19 Vaccine	Congestive Heart Failure / Enlarged Heart / Heart Palpitations	1
COVID-19 Vaccine	Constant Diarrhea	1
COVID-19 Vaccine	Constant Pain and Numbness in Fingers and Arm	1
COVID-19 Vaccine	Constipation / Indigestion / Abdominal Pain / Fatigue / Dizziness / Headache / Nausea / Vomiting / Chest Pains	1
COVID-19 Vaccine	Cord Compression Myelopathy	1
COVID-19 Vaccine	Cornea Transplant	1
COVID-19 Vaccine	Cough / Cold symptoms	1
COVID-19 Vaccine	Coughing Blood / Severe Chest Pain / Severe Burning Sensation / Blood Clots / Difficulty Breathing	1
COVID-19 Vaccine	COVID Arm / Extreme Fatigue / Joint and Muscle Pain / High Blood Pressure / Heart Irregularities	1
COVID-19 Vaccine	COVID Pneumonia	2
COVID-19 Vaccine	Creutzfeldt-Jacobs	1
COVID-19 Vaccine	Deafness	1
COVID-19 Vaccine	Deafness (Right Side)	1
COVID-19 Vaccine	Death	53
COVID-19 Vaccine	Death / Guillain-Barré Syndrome (GBS)	2
COVID-19 Vaccine	Death / Thrombocytopenia	1
COVID-19 Vaccine	Decreased Heart Rate / Low Blood Pressure	1
COVID-19 Vaccine	Deep Vein Thrombosis (DVT)	9
COVID-19 Vaccine	Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE)	4
COVID-19 Vaccine	Dermatomyositis	1
COVID-19 Vaccine	Difficulty Breathing	3
COVID-19 Vaccine	Difficulty Breathing / Coughing Blood / Swollen	1

	Legs	
COVID-19 Vaccine	Difficulty Breathing / Migraine / Chills / Muscle Pain	1
COVID-19 Vaccine	Difficulty Breathing / Muscle Tension	1
COVID-19 Vaccine	Difficulty Breathing / Nausea / Dizziness / Weakness / Loss of Appetite / Rash / Pain	1
COVID-19 Vaccine	Difficulty Breathing / Nausea / Paralysis / Dizziness	1
COVID-19 Vaccine	Difficulty Breathing / Numbness	1
COVID-19 Vaccine	Difficulty Breathing / Pneumonia / Body Aches / Headaches / Blurred Vision / Dizziness / Weakness	1
COVID-19 Vaccine	Difficulty Breathing and Speaking / Disorientation / Muscle Weakness	1
COVID-19 Vaccine	Disoriented / Unresponsive	1
COVID-19 Vaccine	Diverticulitis	1
COVID-19 Vaccine	Dizziness	1
COVID-19 Vaccine	Dizziness / Broken Leg & Ankle	1
COVID-19 Vaccine	Dizziness / Difficulty Breathing / Foggy Thinking / Dehydration / Numbness / Faintness	1
COVID-19 Vaccine	Dizziness / Head Body Injury	1
COVID-19 Vaccine	Dizziness / Headache / Lethargic / Pressure in Head and Brain	1
COVID-19 Vaccine	Dizziness / Headaches / Facial Paralysis	1
COVID-19 Vaccine	Dizziness / Headaches / Loss of Balance	1
COVID-19 Vaccine	Dizziness / Lightheadedness	1
COVID-19 Vaccine	Dizziness / Loss of Sensation	1

COVID-19 Vaccine	Dizziness / Numbness / Rash	1
COVID-19 Vaccine	Dizziness / Shortness of Breath / Burning Sensation	1
COVID-19 Vaccine	Dizziness / Tachycardia / High Blood Pressure	1
COVID-19 Vaccine	Dizziness / Vomiting / High Blood Pressure	1
COVID-19 Vaccine	Dizziness / Skull Fracture / Concussion	1
COVID-19 Vaccine	DVT / Serum Reaction / Paresthesia / Calculus of Kidney / Gross Hematuria	1
COVID-19 Vaccine	Ear Popping / Confusion / Incoherent / Hard to Concentrate and Focus	1
COVID-19 Vaccine	Elevated Blood Pressure	2
COVID-19 Vaccine	Elevated Blood Pressure / Tremors / Dizziness	1
COVID-19 Vaccine	Elevated Blood Pressure and Heart Rate	2
COVID-19 Vaccine	Elevated Heart Rate / Fever	1
COVID-19 Vaccine	Elevated Heart Rate / Low Blood Pressure	1
COVID-19 Vaccine	Elevated Troponin	1
COVID-19 Vaccine	Elevated Troponin / Decreased Platelet Levels	1
COVID-19 Vaccine	Emotional Distress / Psychiatric Breakdown	1
COVID-19 Vaccine	Encephalopathy	1
COVID-19 Vaccine	Enlarged Lymph Nodes	1
COVID-19 Vaccine	Enlarged Lymph Nodes / Fainted / Dizziness / Nausea / Fatigue / Muscle Aches	1
COVID-19 Vaccine	Eosinophil / Hypoalbuminemia / Thrombocytosis	1
COVID-19 Vaccine	Eosinophilia / Systemic Inflammation	1
COVID-19 Vaccine	Erythema	1
COVID-19 Vaccine	Erythema Nodosum	1

COVID-19 Vaccine	Exacerbation of Pre-Existing Condition	1
COVID-19 Vaccine	Extreme Arm and Leg Pain	1
COVID-19 Vaccine	Extreme Dizziness / Fatigue / Broken Back	1
COVID-19 Vaccine	Extreme Fatigue / Brain Fog	1
COVID-19 Vaccine	Extreme Fatigue / Heart Irregularities	1
COVID-19 Vaccine	Extreme Fatigue / Heart Palpitation	1
COVID-19 Vaccine	Extreme Fatigue / Nausea / Dizziness / Nerve Pain / Abdominal Pain	1
COVID-19 Vaccine	Extreme Fatigue / Shortness of Breath / Elevated Blood Pressure / Left Ventricular Cardiomalogy	1
COVID-19 Vaccine	Extreme Fatigue / Swelling and Pain in Lower Extremities	1
COVID-19 Vaccine	Extreme Joint Pain and Swelling	1
COVID-19 Vaccine	Extreme Swelling	1
COVID-19 Vaccine	Eye Stroke	1
COVID-19 Vaccine	Face Spasms / Hypertension	1
COVID-19 Vaccine	Face Swelling / Inflammation / Leg Bruising / Numbness on Neck, Head, Face and Left Hand Fingers / Severe Kidney Pain / Breast Pain	1
COVID-19 Vaccine	Facial Droop / Tremors	1
COVID-19 Vaccine	Facial Numbness	1
COVID-19 Vaccine	Facial Numbness / Migraine	1
COVID-19 Vaccine	Facial Numbness / Tightness In Chest / High Heart Rate	1
COVID-19 Vaccine	Facial Paralysis	1
COVID-19 Vaccine	Facial Spasms	1
COVID-19 Vaccine	Facial Spasms and	1

	Paralysis	
COVID-19 Vaccine	Facial Swelling	1
COVID-19 Vaccine	Facial Swelling / Weakness / Dizziness / Vision Problems / Severe Hypertension	1
COVID-19 Vaccine	Facial Swelling and Burning / Skin Peeling / Fatigue	1
COVID-19 Vaccine	Fainted	13
COVID-19 Vaccine	Fainted / Allergic Reaction / Hives	1
COVID-19 Vaccine	Fainted / Blood Clots	1
COVID-19 Vaccine	Fainted / Broken Nose	1
COVID-19 Vaccine	Fainted / Broken Teeth	1
COVID-19 Vaccine	Fainted / Chills / Joint Pain / Rash	1
COVID-19 Vaccine	Fainted / Convulsions / Confusion / Throat Swelling	1
COVID-19 Vaccine	Fainted / Dizziness / Weakness	1
COVID-19 Vaccine	Fainted / Elbow Injury	1
COVID-19 Vaccine	Fainted / Headache / Chest Pain / Muscle Spasms / Shortness of Breathe / Weakness / Anxiety / High Blood Pressure	1
COVID-19 Vaccine	Fainted / Hematoma / Concussion	1
COVID-19 Vaccine	Fainted / Seizure	2
COVID-19 Vaccine	Fainted / Seizure / Lost Control of Bladder	1
COVID-19 Vaccine	Fainted / Subdural Hematoma	1
COVID-19 Vaccine	Fainted / Vomiting / Convulsions	1
COVID-19 Vaccine	Fainting	8
COVID-19 Vaccine	Fainting / Broken Ankle	1
COVID-19 Vaccine	Fainting / Chin Laceration	1
COVID-19 Vaccine	Fainting / Difficulty Breathing	1

COVID-19 Vaccine	Fainting / Fatigue / Dizziness / Nausea	1
COVID-19 Vaccine	Fainting / Head Injury	1
COVID-19 Vaccine	Fainting / High Blood Pressure / Low Blood Sugar / Severe Migraines	1
COVID-19 Vaccine	Fainting / Injury to Face	1
COVID-19 Vaccine	Fainting / Mouth Injury	1
COVID-19 Vaccine	Fainting / Vomiting / Convulsions	1
COVID-19 Vaccine	Fatigue / Back Pain / Chest Pain / Severe Headache	1
COVID-19 Vaccine	Fatigue / Body Ache / Headache / Uncontrollable Blood Pressure and Heart Rate	1
COVID-19 Vaccine	Fatigue / Brain Fog	1
COVID-19 Vaccine	Fatigue / Dizziness / Nausea / Diarrhea	1
COVID-19 Vaccine	Fatigue / Dizziness / Nausea / Hallucinations / Brain Fog	1
COVID-19 Vaccine	Fatigue / Dizziness / Severe Leg Pain	1
COVID-19 Vaccine	Fatigue / Fever / Malaise / Dehydration / Acute Kidney Injury / Loss of Appetite / Nausea	1
COVID-19 Vaccine	Fatigue / Heart Palpitations	1
COVID-19 Vaccine	Fatigue / Loss of Appetite / Confusion	1
COVID-19 Vaccine	Fatigue / Nausea / Abdominal Pain / Leg Weakness	1
COVID-19 Vaccine	Fatigue / Nausea / Headache / Fever / Body Ache / Sweating	1
COVID-19 Vaccine	Fatigue / Pain / Nausea / Headache	1
COVID-19 Vaccine	Fatigue / Rash / Pain	1
COVID-19 Vaccine	Fatigue / Sore Armpit / Headache / Elevated Heart Rate	1

COVID-19 Vaccine	Feeling Faint / Dizziness	1
COVID-19 Vaccine	Feeling Ill / Blood Pressure Spikes	1
COVID-19 Vaccine	Fever / Abdominal Pain	1
COVID-19 Vaccine	Fever / Aches	1
COVID-19 Vaccine	Fever / Arm Injury	1
COVID-19 Vaccine	Fever / Chest Pain	1
COVID-19 Vaccine	Fever / Chills / Headache / Arm Pain / weakness / Loss of Appetite	1
COVID-19 Vaccine	Fever / Chills / Nausea / Dizziness / Fatigue / Dark Stools	1
COVID-19 Vaccine	Fever / Chills / Severe Chest Pain / Shortness of Breath / Confusion	1
COVID-19 Vaccine	Fever / Chills / Shaking / Weakness	1
COVID-19 Vaccine	Fever / Chills / Shortness of Breath / Rash / Loss of Appetite / Dehydration	1
COVID-19 Vaccine	Fever / Congestion	2
COVID-19 Vaccine	Fever / Delusions / Organ Failure / Extreme Weight Loss / Inability to walk	1
COVID-19 Vaccine	Fever / Difficulty Walking	1
COVID-19 Vaccine	Fever / Headache / Body Pain / Vomiting	1
COVID-19 Vaccine	Fever / High Blood Pressure	1
COVID-19 Vaccine	Fever / Migraine / Vomiting	1
COVID-19 Vaccine	Fever / Nausea / Chills / Blood Clots Enlarged Lymph nodes	1
COVID-19 Vaccine	Fever / Nausea / Difficulty Breathing / Headache	1
COVID-19 Vaccine	Fever / Nausea / Fainted / Tiredness	1
COVID-19 Vaccine	Fever / Septic / Dehydration	1
COVID-19 Vaccine	Fever / Severe Bone and Joint Pain	1

COVID-19 Vaccine	Fever / Severe Head and Neck Pain / Body Aches / Heart Palpitations	1
COVID-19 Vaccine	Fever / Shaking / Broken Teeth	1
COVID-19 Vaccine	Fever / Swelling / Vomiting / Tonsil Edema / Dehydration / Heart Irregularities / Muscle Fatigue / Fatigue	1
COVID-19 Vaccine	Fever / Vomiting / Body Aches	1
COVID-19 Vaccine	Fever / Vomiting / Dehydration	1
COVID-19 Vaccine	Fried Shoulder and Leg Muscles / Swollen Hands / Ankle Pain	1
COVID-19 Vaccine	Flare Up of Rheumatoid Arthritis	1
COVID-19 Vaccine	Flu Like Symptoms / Dehydration	1
COVID-19 Vaccine	Frozen Shoulder	3
COVID-19 Vaccine	Frozen Shoulder / Tendinosis	1
COVID-19 Vaccine	Gastritis	1
COVID-19 Vaccine	Grand Mal Seizure	2
COVID-19 Vaccine	Guillain-Barré Syndrome (GBS)	30
COVID-19 Vaccine	Guillain-Barré Syndrome (GBS) / Death	1
COVID-19 Vaccine	Hand and Arm Numbness / Knots Under Skin / Joint Pain	1
COVID-19 Vaccine	Hand and Arm Numbness and Tingling / Rapid Heartbeat	1
COVID-19 Vaccine	Head Injury	1
COVID-19 Vaccine	Headache	1
COVID-19 Vaccine	Headache / Bilateral Neuropathy / Skin Discoloration	1
COVID-19 Vaccine	Headache / Blindness	1
COVID-19 Vaccine	Headache / Blood Pressure Drop / Dizziness	1

COVID-19 Vaccine	Headache / Fatigue / Chest Pressure	1
COVID-19 Vaccine	Headache / Leg Swelling / Pain / Blood Clots / Rare Blood Disease / Pneumonia	1
COVID-19 Vaccine	Headache / Muscle Ache / Rash / Rapid Heartbeat / Fever	1
COVID-19 Vaccine	Headache / Nausea / Diarrhea	1
COVID-19 Vaccine	Headache / Vomiting / Ketoacidosis	1
COVID-19 Vaccine	Headache / Weakness / Tinnitus	1
COVID-19 Vaccine	Headaches / Body Aches / Blood Clots	1
COVID-19 Vaccine	Headaches / Dizziness	1
COVID-19 Vaccine	Headaches / Extreme Leg Weakness	1
COVID-19 Vaccine	Headaches / Fatigue	1
COVID-19 Vaccine	Headaches / Muscle Cramps	1
COVID-19 Vaccine	Headaches / Rash	1
COVID-19 Vaccine	Headaches / Rashes / High Blood Pressure	1
COVID-19 Vaccine	Headaches / Tinnitus / Extreme Fatigue	1
COVID-19 Vaccine	Headaches / Tinnitus / Lightheadedness / Blurred Vision / Dizziness / Weakness	1
COVID-19 Vaccine	Hearing Loss	13
COVID-19 Vaccine	Hearing Loss / High Blood Pressure	1
COVID-19 Vaccine	Hearing Loss / Vocal Cord Paralysis / Fatigue / Neck Pain / Numbness / Head Pressure	1
COVID-19 Vaccine	Heart Attack	6
COVID-19 Vaccine	Heart Attack / Death	1
COVID-19 Vaccine	Heart Failure	1
COVID-19 Vaccine	Heart Failure / Atrial	1

	Fibrillation	
COVID-19 Vaccine	Heart Failure / Renal Failure	1
COVID-19 Vaccine	Heart Fibrillation	1
COVID-19 Vaccine	Heart Inflammation	1
COVID-19 Vaccine	Heart Issues / Stroke	1
COVID-19 Vaccine	Heart Palpitations	3
COVID-19 Vaccine	Heart Palpitations / Heartburn / Buzzing / Chest Pain	1
COVID-19 Vaccine	Heart Palpitations / Light Headedness	1
COVID-19 Vaccine	Heart Palpitations / Shaking / Shortness of Breath	1
COVID-19 Vaccine	Heart Racing / Palpitations / Fluttering	1
COVID-19 Vaccine	Heavy Vaginal Bleeding	1
COVID-19 Vaccine	Hemorrhagic Stroke	1
COVID-19 Vaccine	Herpes Zoster / Supraclavicular Lymphadenopathy	1
COVID-19 Vaccine	Herpes Zoster / Transverse Myelitis	1
COVID-19 Vaccine	Hidradenitis Suppurativa	1
COVID-19 Vaccine	High Blood pressure	3
COVID-19 Vaccine	High Blood Pressure / Chest Tightness / Headaches / Inability to Focus	1
COVID-19 Vaccine	High Blood Pressure / Chronic Headaches / Vertigo / Chest Pains / Ear Pain and Pressure / Eye pain / Changes in Vision	1
COVID-19 Vaccine	High Blood Pressure / Dizziness / Difficulty Breathing	1
COVID-19 Vaccine	High Blood Pressure / Facial Swelling and Numbness	1
COVID-19 Vaccine	High Blood Pressure / Fever / Seizure / Short	1

	Term Memory Loss / Numbness and Aches	
COVID-19 Vaccine	High Blood Pressure / Pain Neck, Chest, Back and Arm	1
COVID-19 Vaccine	High Blood Pressure / Severe Dizziness	1
COVID-19 Vaccine	High Blood Pressure / Tachycardia / Shortness of Breathe / Severe Headache	1
COVID-19 Vaccine	High Heart Rate / Brain Fog / Chronic Fatigue	1
COVID-19 Vaccine	High Pitched Sound in Ears / Insomnia	1
COVID-19 Vaccine	Hives	2
COVID-19 Vaccine	Hives / Difficulty Breathing	1
COVID-19 Vaccine	Hives / Fatigue / Headache / Tremors / Weakness	1
COVID-19 Vaccine	Hives / Fatigue / Vomiting / Tremors	1
COVID-19 Vaccine	Hives / Headache Swelling / Dizziness	1
COVID-19 Vaccine	Hives / Skin Discoloration	1
COVID-19 Vaccine	Hives / Urticaria / Angioedema	1
COVID-19 Vaccine	Hypertension	1
COVID-19 Vaccine	Hypertension / Tachycardia	1
COVID-19 Vaccine	Hypoglossal Nerve Palsy	1
COVID-19 Vaccine	Hypotension	1
COVID-19 Vaccine	Idiopathic Intracranial Hypertension / Esotropia	1
COVID-19 Vaccine	Idiopathic/Immune Thrombocytopenia Purpura (ITP)	8
COVID-19 Vaccine	Inability to Stand / Walk / Do Daily Routines	1
COVID-19 Vaccine	Increased Heart Rate / Convulsions / Severe Headache / Unable to Walk or Stand / Light Sensitivity	1
COVID-19 Vaccine	Infectious Cellulitis	1
COVID-19 Vaccine	Inflamed Lymph Nodes	1

COVID-19 Vaccine	Inflamed Rotator Cuff	1
COVID-19 Vaccine	Inflammation / High Blood Pressure and Heart Rate / Rash / Hives / Trouble Breathing	1
COVID-19 Vaccine	Inflammation / Swelling / Extreme Pain	1
COVID-19 Vaccine	Inflammation in Hands and Wrists	1
COVID-19 Vaccine	Inflammatory Arthritis	1
COVID-19 Vaccine	Inflammatory Myelitis	1
COVID-19 Vaccine	Insomnia	1
COVID-19 Vaccine	Intense Chest Pains	1
COVID-19 Vaccine	Internal Bleeding / Mouth Blisters	1
COVID-19 Vaccine	Interstitial Lung Disease / Chronic Respiratory Failure	1
COVID-19 Vaccine	Irregular Heart Beat / Heart Failure	1
COVID-19 Vaccine	Irregular Heart Rhythm / Tachycardia / Severe Chest Pain / Left Side Numbness	1
COVID-19 Vaccine	Ischemic Colitis	2
COVID-19 Vaccine	Ischemic Stroke	3
COVID-19 Vaccine	Itching / Rash / Nausea / Vomiting	1
COVID-19 Vaccine	ITP / Chronic Bleeding Disorder	1
COVID-19 Vaccine	Jaundice / Lethargy / Loss of Appetite	1
COVID-19 Vaccine	Jaw, Chest and Neck Pain / Chest Pressure / Shortness of Breath / Extreme Nausea	1
COVID-19 Vaccine	Joint Inflammation	1
COVID-19 Vaccine	Joint Inflammation / Joint Pain	1
COVID-19 Vaccine	Joint Pain and Swelling	1
COVID-19 Vaccine	Kidney Injury / Arm Injury	1
COVID-19 Vaccine	Kidney Stones	1
COVID-19 Vaccine	Left / Right Leg Numbness	1

COVID-19 Vaccine	Left Arm and Hand Numbness	1
COVID-19 Vaccine	Left Perilymphatic Fistula / Right Perilymphatic Fistula / Elevated Intracranial Pressure / Bilateral Eustachian Tube Dysfunction	1
COVID-19 Vaccine	Left Side Numbness / Back Pain / Ear Pain / Drooling / Brain Fog	1
COVID-19 Vaccine	Left Side Numbness / Fainted	1
COVID-19 Vaccine	Left Side Numbness / Knee and Leg Pain	1
COVID-19 Vaccine	Left Side Paralysis	1
COVID-19 Vaccine	Left Side Weakness	1
COVID-19 Vaccine	Left Side Weakness / Difficulty Breathing / Migraine / Heart Palpitations / Wheezing / Dizziness / Joint Pain	1
COVID-19 Vaccine	Leg Pain	1
COVID-19 Vaccine	Leg Pain / Chest Pain	1
COVID-19 Vaccine	Lesions	1
COVID-19 Vaccine	Leukoycto Clastic Vasculitis with Dermal Neutrophil	1
COVID-19 Vaccine	Lichen Planus	1
COVID-19 Vaccine	Light Headedness / Extreme Fatigue / Faintness	1
COVID-19 Vaccine	Lightheaded / Cold Sweat / Chills	1
COVID-19 Vaccine	Lightheaded / Dizziness / Nausea	1
COVID-19 Vaccine	Lightheaded / Throat Swelling / Difficulty Breathing	1
COVID-19 Vaccine	Lipoma of Subcutaneous Tissue (Left Arm)	1
COVID-19 Vaccine	Liver Damage	1
COVID-19 Vaccine	Liver Injury	1
COVID-19 Vaccine	LLE / LUE Weakness / Facial Numbness /	1

	Difficulty Speaking	
COVID-19 Vaccine	Loss of Body Functions	1
COVID-19 Vaccine	Loss of Eye Sight	1
COVID-19 Vaccine	Loss of Sensation in Extremities / Tinnitus / Headache	1
COVID-19 Vaccine	Lost Consciousness	1
COVID-19 Vaccine	Low Blood Pressure / Chest Pain	1
COVID-19 Vaccine	Low Blood Pressure / Difficulty Breathing	1
COVID-19 Vaccine	Low Blood Pressure / Fluid In Lungs / Pancreatitis	1
COVID-19 Vaccine	Low Blood Sugar / Low Blood Pressure / Low Energy / Pneumonia	1
COVID-19 Vaccine	Low Hemoglobin	1
COVID-19 Vaccine	Low O2 Saturation	1
COVID-19 Vaccine	Low Oxygen / Fatigue	1
COVID-19 Vaccine	Low Platelet Count	1
COVID-19 Vaccine	Lung Infection	1
COVID-19 Vaccine	Lung Nodules / Migraine	1
COVID-19 Vaccine	Lymph Node Mass	1
COVID-19 Vaccine	Memory Loss / Hallucinating	1
COVID-19 Vaccine	Meningitis / Syringomyelia	1
COVID-19 Vaccine	Mesenteric Venous Thrombosis	1
COVID-19 Vaccine	Migraine / Chronic Fatigue	1
COVID-19 Vaccine	Mesenteric Venous Thrombosis / Septic Thrombophlebitis	1
COVID-19 Vaccine	Migraine / Joint Pain / Fatigue	1
COVID-19 Vaccine	Migraine Headache	2
COVID-19 Vaccine	Migraine Headaches / High Blood Pressure	1
COVID-19 Vaccine	Mild Heart Attack	1
COVID-19 Vaccine	Miscarriage	1

COVID-19 Vaccine	Multisystem Inflammatory Syndrome	1
COVID-19 Vaccine	Muscle Aches / Swelling / Cough / Chills / Night Sweats / Dizziness / Elevated WBC / Stomach Ache / Fatigue / Difficulty Ambulating	1
COVID-19 Vaccine	Muscle Pain / Body Aches	1
COVID-19 Vaccine	Muscle Spasms / Breathing Abnormality / Pain	1
COVID-19 Vaccine	Myasthenia Gravis Disease	2
COVID-19 Vaccine	Myocarditis	19
COVID-19 Vaccine	Myocarditis / Heart Attack	1
COVID-19 Vaccine	Myocarditis / Pericarditis	5
COVID-19 Vaccine	Myocarditis / Pneumonia	1
COVID-19 Vaccine	Myoclonus Seizures / Uncontrollable Laughter / Fatigue / Headaches / Loss of Taste, Appetite, Weight / High Blood Pressure / Tinnitus / Ingrown Nails / Blurry Vision / Constipation / Dehydration / Confusion / Numbness	1
COVID-19 Vaccine	Myopericarditis	5
COVID-19 Vaccine	Nausea / Chest Pains / Migraines / Numbness	1
COVID-19 Vaccine	Nausea / Diarrhea / Headache / Sweating	1
COVID-19 Vaccine	Nausea / Dizziness / Difficulty Breathing / Fever / Sweating	1
COVID-19 Vaccine	Nausea / Facial Pain / Trouble Thinking / Pain in Shoulders and Knees / Heart Fluttering	1
COVID-19 Vaccine	Nausea / Fatigue / Tongue Swelling / Neck and Shoulder Pain	1
COVID-19 Vaccine	Nausea / Fever / Shortness of Breath	1
COVID-19 Vaccine	Nausea / Hives / Shaking	1
COVID-19 Vaccine	Nausea / Right Limb Weakness / Vomiting / Memory Loss / Confusion	1

COVID-19 Vaccine	Nausea / Vomiting / Diarrhea / Leg and Knee Pain / Encephalopathy	1
COVID-19 Vaccine	Nausea / Vomiting / Diarrhea / Loss of Appetite / Weight Loss / Malnutrition	1
COVID-19 Vaccine	Nausea / Vomiting / Headache / Difficulty Breathing	1
COVID-19 Vaccine	Nausea / Vomiting / Lethargy	1
COVID-19 Vaccine	Nerve Damage	1
COVID-19 Vaccine	Nerve Damage / Muscle Atrophy	1
COVID-19 Vaccine	Nerve Pain / Vision Weakness / Muscle Fatigue / Headache	1
COVID-19 Vaccine	Neurologic / Cardiovascular / Gynecologic Issues	1
COVID-19 Vaccine	Neurologic Disorder	1
COVID-19 Vaccine	Neurologic Symptoms	2
COVID-19 Vaccine	Neurological Damage	1
COVID-19 Vaccine	Neurological Reaction / Paresthesia	1
COVID-19 Vaccine	Neuropathy / Joint Pain / Palpitations	1
COVID-19 Vaccine	Night Sweats / Fatigue / Nausea / Vomiting / Diarrhea	1
COVID-19 Vaccine	Non-specific Paresthesia	1
COVID-19 Vaccine	Not Specified	58
COVID-19 Vaccine	Numbness	2
COVID-19 Vaccine	Numbness / Bruising / Pain	1
COVID-19 Vaccine	Numbness / Pain / Tingling / Inability to Stand or Walk	1
COVID-19 Vaccine	Numbness / Swelling / Chest Pain	1
COVID-19 Vaccine	Numbness / Weakness in Legs	1
COVID-19 Vaccine	Numbness and Bruising	1

COVID-19 Vaccine	Numbness in Feet	1
COVID-19 Vaccine	Numbness on Entire Left Side	1
COVID-19 Vaccine	Open Wound / Hand & Foot / COVID Pneumonia / Enlarged Lymph Nodes	1
COVID-19 Vaccine	Optic Migraine	1
COVID-19 Vaccine	Pain / Headache / Facial Distortion	1
COVID-19 Vaccine	Pain / Mouth Infection	1
COVID-19 Vaccine	Pain / Nausea / Dizziness / Fainting	1
COVID-19 Vaccine	Pain / Numbness / Weakness in Arm	1
COVID-19 Vaccine	Pain / Skin Lesions	1
COVID-19 Vaccine	Pain in Shins and Ankles	1
COVID-19 Vaccine	Pain Throughout Body	1
COVID-19 Vaccine	Pancolitis / C. Diff. Infection	1
COVID-19 Vaccine	Pancreatitis	1
COVID-19 Vaccine	Pancytopenia	1
COVID-19 Vaccine	Paralysis	6
COVID-19 Vaccine	Paralysis / Pain / Headaches	1
COVID-19 Vaccine	Paralyzed Vocal Cord	1
COVID-19 Vaccine	Paresthesia	3
COVID-19 Vaccine	Paresthesia / Nerve Pain / Muscle and Joint Pain / Weakness / Tongue Tingling / Eye Irritation	1
COVID-19 Vaccine	Parsonage Turner Syndrome (PTS)	3
COVID-19 Vaccine	Passed Out	1
COVID-19 Vaccine	Pericardial Enhancement	1
COVID-19 Vaccine	Pericarditis	17
COVID-19 Vaccine	Pericardium Cyst	1
COVID-19 Vaccine	Peripheral Neuropathy	1
COVID-19 Vaccine	Petchiae / Low Platelets / Splenectomy	1

COVID-19 Vaccine	Petechiae	1
COVID-19 Vaccine	Petechiae / Bleeding	1
COVID-19 Vaccine	Petechiae / Headache / Nausea	1
COVID-19 Vaccine	Phantosmia	1
COVID-19 Vaccine	Pneumonia	1
COVID-19 Vaccine	Pneumonia / Bronchitis	1
COVID-19 Vaccine	Pneumonia / Decreased Potassium	1
COVID-19 Vaccine	Poisoning by Vaccine and Biological Substances	1
COVID-19 Vaccine	Polymyalgia Rheumatica	1
COVID-19 Vaccine	Polymyositis	1
COVID-19 Vaccine	Polyneuropathy / Critical Illness Myopathy	1
COVID-19 Vaccine	Post Stroke Recudence	1
COVID-19 Vaccine	Posterior Leukoencephalopathy	1
COVID-19 Vaccine	Postural Orthostatic Tachycardia Syndrome (POTS)	2
COVID-19 Vaccine	Pressure in Head and Neck / Chest Pain / Blood Clots	1
COVID-19 Vaccine	Primary Sclerosing Cholangitis	1
COVID-19 Vaccine	Psoriasis / Moderate Osteoarthritis	1
COVID-19 Vaccine	Psoriasis / Onycholysis / Edema / Xerosis	1
COVID-19 Vaccine	Psychosis	1
COVID-19 Vaccine	Ptosis / Palsy	2
COVID-19 Vaccine	Pulmonary Embolism	19
COVID-19 Vaccine	Pulmonary Embolism / Blood Clots / Heart Strain	1
COVID-19 Vaccine	Pulmonary Embolism / Hypothyroidism / Generalized Joint Pain	1
COVID-19 Vaccine	Pulmonary Embolism / Lung Infarction / Hypercoagulability	1

COVID-19 Vaccine	Queasy Feeling	1
COVID-19 Vaccine	Quincke Edema / Injection Site Injury / Fever / Swelling	1
COVID-19 Vaccine	Radial Artery Thrombus / Angina	1
COVID-19 Vaccine	Rapid Heart Rate	1
COVID-19 Vaccine	Rapid Heart Rate / Difficulty Breathing	1
COVID-19 Vaccine	Rapid Heartbeat	4
COVID-19 Vaccine	Rash	15
COVID-19 Vaccine	Rash / Allergic Reaction	1
COVID-19 Vaccine	Rash / Elevated Heart Rate / Chest Pain / Dizziness	1
COVID-19 Vaccine	Rash / Hives	1
COVID-19 Vaccine	Rash / Nerve Pain	1
COVID-19 Vaccine	Rash / Shortness of Breath / Rapid Heartbeat / Dizziness / Fainted / Joint Pain / Headache	1
COVID-19 Vaccine	Rash / Swelling	2
COVID-19 Vaccine	Rashes	1
COVID-19 Vaccine	Recurring Epistaxis	1
COVID-19 Vaccine	Respiratory Failure / Influenza A / Necrotizing Pneumonia / Acute Kidney Injury	1
COVID-19 Vaccine	Rhabdomyolysis / Dizziness / Chest Pain / Right Bundled Branch Block	1
COVID-19 Vaccine	Rheumatoid Arthritis	1
COVID-19 Vaccine	Right Dural Venus Thrombosis	1
COVID-19 Vaccine	Right Side Numbness / Loss of Voice / Bowel Movement Issues	1
COVID-19 Vaccine	Right Side Numbness / Nausea / Dizziness	1
COVID-19 Vaccine	Right Side Paralysis	1
COVID-19 Vaccine	Robust Reactions	1

COVID-19 Vaccine	Rotator Cuff Tear	1
COVID-19 Vaccine	Rotator Cuff Tear / Advanced Tendinopathy / Left Shoulder Capsulitis	1
COVID-19 Vaccine	Ruptured Tendon	1
COVID-19 Vaccine	Seizure / Dysphagia	1
COVID-19 Vaccine	Seizures	11
COVID-19 Vaccine	Sepsis	1
COVID-19 Vaccine	Severe Abdominal Pain	1
COVID-19 Vaccine	Severe Allergic Reaction	14
COVID-19 Vaccine	Severe Anaphylaxis	1
COVID-19 Vaccine	Severe Aplastic Anemia	1
COVID-19 Vaccine	Severe Arm Pain	1
COVID-19 Vaccine	Severe Arm Pain / Fainting	1
COVID-19 Vaccine	Severe Arm Pain / Rapid Heartbeat	1
COVID-19 Vaccine	Severe Back, Neck and Head Pain	1
COVID-19 Vaccine	Severe Bruising / Arm Pain	1
COVID-19 Vaccine	Severe Chest and Abdominal Pain	1
COVID-19 Vaccine	Severe Chest and Head Pain	1
COVID-19 Vaccine	Severe Chest Pain	1
COVID-19 Vaccine	Severe Chest Pain / Shortness of Breath / Migraine like Pain / Seizure / Dizziness / Light Sensitivity / Dry Mouth / Hoarse Throat / Tingling / Numbness	1
COVID-19 Vaccine	Severe Chills / Pain / Fever / Vomiting / Fainted	1
COVID-19 Vaccine	Severe Chronic Pain	1
COVID-19 Vaccine	Severe Fatigue / Fever / Chills / Pain	1
COVID-19 Vaccine	Severe Flu Like Symptoms	1
COVID-19 Vaccine	Severe Groin, Knee, Elbow and Hand Pain	1
COVID-19 Vaccine	Severe Headache / Body	1

	Aches / Difficulty Concentrating / Photo Sensitivity	
COVID-19 Vaccine	Severe Headache / Chills / Nausea / Vomiting / Fatigue	1
COVID-19 Vaccine	Severe Headache / Elevated Blood Pressure and Pulse / Abdominal Pain	1
COVID-19 Vaccine	Severe Headaches / Tingling / Numbness	1
COVID-19 Vaccine	Severe Itching / Allergic Reaction	1
COVID-19 Vaccine	Severe Itching / Blisters	1
COVID-19 Vaccine	Severe Joint Pain / Fever / Asthma	1
COVID-19 Vaccine	Severe Leg and Back Pain / Extreme Fatigue	1
COVID-19 Vaccine	Severe Leg Pain	1
COVID-19 Vaccine	Severe Lower Back Pain / Dizziness / Headaches	1
COVID-19 Vaccine	Severe Migraines / Pain / Fatigue	1
COVID-19 Vaccine	Severe Muscle Pain / Internal Bleeding	1
COVID-19 Vaccine	Severe Nausea / Dizziness / Dehydration	1
COVID-19 Vaccine	Severe Pain and Fatigue	1
COVID-19 Vaccine	Severe Pain and Weakness in Shoulder and Arm	1
COVID-19 Vaccine	Severe Rash / Hives	1
COVID-19 Vaccine	Severe Rashes	1
COVID-19 Vaccine	Severe Reaction / Low Heart Rate	1
COVID-19 Vaccine	Severe Tinnitus / Dizziness	1
COVID-19 Vaccine	Severe Vaginal Bleeding	1
COVID-19 Vaccine	Severe Vasculitis	1
COVID-19 Vaccine	Severe Vertigo / Leg Cramps / Exhaustion / Night Sweats / Headaches	1
COVID-19 Vaccine	Shaking / Muscle	1

	Weakness / Nerve Pain / GBS like symptoms	
COVID-19 Vaccine	Shaking / Numbness / Swelling / Severe Chest Pressure and Pressure / Sweating	1
COVID-19 Vaccine	Shaking / Swelling / Headaches	1
COVID-19 Vaccine	Shingles	6
COVID-19 Vaccine	Shingles / COVID-19	1
COVID-19 Vaccine	Shocking Sensation in Arteries or Veins / Fatigue / Flu Like Symptoms / Pain in Stomach and Legs	1
COVID-19 Vaccine	Shortness of Breath / Arm Injury	1
COVID-19 Vaccine	Shortness of Breath / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Chest Pains / Extreme Swelling	1
COVID-19 Vaccine	Shortness of Breath / Chest Pressure / Tingling in Hands and Feet	1
COVID-19 Vaccine	Shortness of Breath / Confusion / Severe Headache	1
COVID-19 Vaccine	Shortness of Breath / Fast Heartbeat / Panic Attack / Shoulder Pain / Anxiety / Frozen Extremities / Dizziness	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / COVID Pneumonia	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / Fever/ Headache / Body Ache	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / Heavy Limbs	1
COVID-19 Vaccine	Shortness of Breath / Fever / Chills / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Racing Heartbeat	1
COVID-19 Vaccine	Shortness of Breath / Rapid Heartbeat / Dizziness	1

COVID-19 Vaccine	Shortness of Breath / Rash / Migraine	1
COVID-19 Vaccine	Shortness of Breath / Shivering / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Sore Muscles / Chest Pains / Flu Like Symptoms	1
COVID-19 Vaccine	Shortness of Breath / Swelling / High Blood Pressure / Heart Problems / Anxiety	1
COVID-19 Vaccine	Shortness of Breath / Wheezing / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Heart Palpitations/ Leg Pain / Dizziness	1
COVID-19 Vaccine	Shoulder / Arm Injury	9
COVID-19 Vaccine	Shoulder Injury	25
COVID-19 Vaccine	Shoulder Pain	8
COVID-19 Vaccine	Sinusitis	1
COVID-19 Vaccine	SIRVA	7
COVID-19 Vaccine	Sixth Nerve Palsy	1
COVID-19 Vaccine	Skin and Gum Sensitivity / Anal Fistulas	1
COVID-19 Vaccine	Skin Rash / Muscle Weakness	1
COVID-19 Vaccine	Slurred Speech / Face Drooping / Tingling in Face	1
COVID-19 Vaccine	Small Fiber Neuropathy	2
COVID-19 Vaccine	Spasms / Cramps / Swollen Tongue / Shingles	1
COVID-19 Vaccine	Spinal Meningitis	1
COVID-19 Vaccine	Spongiotic Dermatitis	1
COVID-19 Vaccine	Stevens Johnson Syndrome	1
COVID-19 Vaccine	Stiff Neck / Migraine	1
COVID-19 Vaccine	Stroke	28
COVID-19 Vaccine	Stroke / Blood Clots	1
COVID-19 Vaccine	Stroke / Death	1
COVID-19 Vaccine	Stroke Like Symptoms	3

COVID-19 Vaccine	Stroke Like Symptoms / Collapsed Lung	1
COVID-19 Vaccine	Subacromial Bursitis	1
COVID-19 Vaccine	Subarachnoid Hemorrhage / Seizure / Traumatic Brain Injury	1
COVID-19 Vaccine	Subcutaneous Sarcoidosis	1
COVID-19 Vaccine	Sudden Hearing Loss (SSHL) / Sudden Deafness	1
COVID-19 Vaccine	Sulphur Taste and Smell	1
COVID-19 Vaccine	Supraventricular Tachycardia	2
COVID-19 Vaccine	Swelling	1
COVID-19 Vaccine	Swelling / Burning / Inflammation	1
COVID-19 Vaccine	Swelling / Headaches / Bad Dreams / Drowsiness / Stroke / Low Blood Pressure	1
COVID-19 Vaccine	Swelling / Hives	1
COVID-19 Vaccine	Swelling / Rash / Skin Peeling	1
COVID-19 Vaccine	Swelling / Trouble Breathing	1
COVID-19 Vaccine	Swollen and Inflamed Lymph Nodes / Cystic Nodule	1
COVID-19 Vaccine	Swollen Ankle	1
COVID-19 Vaccine	Swollen Feet, Arms and Tongue	1
COVID-19 Vaccine	Swollen Finger	1
COVID-19 Vaccine	Swollen Hands / Tingling / Nerve Pain / Eczema	1
COVID-19 Vaccine	Swollen Lymph Nodes	4
COVID-19 Vaccine	Swollen Lymph Nodes / Asthma	1
COVID-19 Vaccine	Syncope	4
COVID-19 Vaccine	Syncope / Concussion / Cheek Bone & Teeth Fractures	1
COVID-19 Vaccine	Syncope / Confusion / Headaches	1

COVID-19 Vaccine	Syncope / Face Head and Nose Injury	1
COVID-19 Vaccine	Syncope / Hypertension / Ischemic Tachycardia / Non-Ischemic Cardiomyopathy / Non-sustained Ventricular Tachycardia / Atrial Fibrillation / Pulmonary Interstitial Edema	1
COVID-19 Vaccine	Systemic Inflammatory Response Syndrome (SIRS)	2
COVID-19 Vaccine	Tachycardia	5
COVID-19 Vaccine	Tachycardia / Diaphoretic	1
COVID-19 Vaccine	Tachycardia / Hypertension / Palpitation	1
COVID-19 Vaccine	Tachycardia / Shortness of Breath / Tremors / Hot Flashes / Paresthesia / Blurred Vision / Near Syncope / Muscle Tension	1
COVID-19 Vaccine	Throat Inflammation / Muscle Pain / Fever	1
COVID-19 Vaccine	Throat Swelling	1
COVID-19 Vaccine	Throat Swelling / Itching / Redness / Heavy Menstrual Flow / Headache / Fatigue / Numbness / Arm Pain	1
COVID-19 Vaccine	Throat Swelling / Tachycardia / Heart Palpitations	1
COVID-19 Vaccine	Throat Tongue Hand and Arm Swelling / Lesions	1
COVID-19 Vaccine	Thrombocytopenia	3
COVID-19 Vaccine	Thrombocytopenia / Cellulitis	1
COVID-19 Vaccine	Thrombosis	2
COVID-19 Vaccine	Thrush / Swollen Tongue, Plate and Gums	1
COVID-19 Vaccine	Thrush / Symptoms of Systemic Inflammatory Response Syndrome	1
COVID-19 Vaccine	Thyroid Storm	1
COVID-19 Vaccine	TIA Stroke	2

COVID-19 Vaccine	Tingling / Numbness / Paralysis	1
COVID-19 Vaccine	Tingling / Rash / Rapid Heartbeat	1
COVID-19 Vaccine	Tinnitus	9
COVID-19 Vaccine	Tinnitus / Hearing Loss	2
COVID-19 Vaccine	Tinnitus / Vertigo / Vomiting	1
COVID-19 Vaccine	Tonsillitis	1
COVID-19 Vaccine	Transient Global Amnesia	1
COVID-19 Vaccine	Transverse Myelitis	8
COVID-19 Vaccine	Transverse Myelitis / GBS	1
COVID-19 Vaccine	Trigger Finger	1
COVID-19 Vaccine	TTS	1
COVID-19 Vaccine	Ulcerative Colitis	1
COVID-19 Vaccine	Unable to Breathe / Unresponsive	1
COVID-19 Vaccine	Unable to Walk	1
COVID-19 Vaccine	Unresponsive / Foaming at Mouth / Low Blood Pressure	1
COVID-19 Vaccine	Unresponsive / Tachycardia / Low Heart Rate / Pain	1
COVID-19 Vaccine	UTI	1
COVID-19 Vaccine	Vaccine Induced Axillary Lymphadenopathy	1
COVID-19 Vaccine	Vasculitis	1
COVID-19 Vaccine	Vasculitis / Trouble Swallowing Food / Weakness	1
COVID-19 Vaccine	Vasovagal Syncope	4
COVID-19 Vaccine	Vertigo / Brain Fog	1
COVID-19 Vaccine	Vertigo / Dizziness / Lightheadedness / Low Energy	1
COVID-19 Vaccine	Vertigo / Migraine	1
COVID-19 Vaccine	Vertigo / Vomiting	1
COVID-19 Vaccine	Vestibular Neuritis	4

COVID-19 Vaccine	Vestibular Neuritis / Migraines / Severe Inflammation	1
COVID-19 Vaccine	Vestibular Neuritis / Tinnitus	1
COVID-19 Vaccine	Vision Loss	5
COVID-19 Vaccine	Vision Loss / Fainted	1
COVID-19 Vaccine	Vision Loss / Muscle Spasms / High Blood Pressure	1
COVID-19 Vaccine	Vision Loss/ Balance Issues / Headaches / Fatigue / Vertigo / Chest Tightness	1
COVID-19 Vaccine	Vocal Cord Dysfunction	1
COVID-19 Vaccine	Vomiting / Fever / Dehydration / Rapid Heartbeat	1
COVID-19 Vaccine	Vomiting / Shortness of Breath	1
COVID-19 Vaccine	Vomiting / Shortness of Breath / Tachycardia	1
COVID-19 Vaccine	VTE / DVT	1
COVID-19 Vaccine	Weakness / Breathing Difficulty / Difficulty Swallowing and Chewing / Double Vision	1
COVID-19 Vaccine	Weakness / Difficulty Walking	2
COVID-19 Vaccine	Weakness / Difficulty Walking / Extreme Body Aches	1
COVID-19 Vaccine	Weakness / Fatigue / Fever / Muscle Pain / Headaches / Chills / Cold Sweats / Cognitive Issues / Chest Tightness / Shortness of Breath / Numbness	1
COVID-19 Vaccine	Weakness / Fatigue / Heart and Blood Pressure Issues	1
COVID-19 Vaccine	Wheezing / Coughing / Shortness of Breath / Blurred Vision	1
COVID-19 Vaccine	Wheezing / Lightheadedness / Dizziness / Metal Taste in Mouth	1

COVID-19 Vaccine	Wheezing / Muscle Weakness / Migraine / Hypertension	1
COVID-19 Vaccine / Remdesivir	Death	1
Decadron / Remdesivir	Death	1
Delay or Failure to Provide Proper Medication and Treatment	Death	1
Dexamethasone	Death	1
Dexamethasone / Doxycycline / Piperacillin-Tazobactam	Death	1
Dexamethasone / Remdesivir	Death	1
Extracorporeal Membrane Oxygenation Machine	Death	1
Failure to Abide by COVID-19 Regulations	Death	1
Hydroxychloroquine	Death	18
Hydroxychloroquine / Azithromycin	Death	1
Hydroxychloroquine / Dexamethasone / Dialysis	Death	1
Hydroxychloroquine / Fentanyl / Intubation	Death	1
Hydroxychloroquine / Medrol	Death	1
Hydroxychloroquine / Odansetron	Death	1
Hydroxychloroquine / Remdesivir	Death	5
Hydroxychloroquine / Remdesivir / Convalescent Plasma	Death	1
Hydroxychloroquine / Sarilumab	Death	1
Hydroxychloroquine / Solu-Medrol / Tocilizumab	Death	2
Intubation	Death	4
Mefloquine	Dizziness / Hearing Loss / PTSD / Tinnitus / Temperature Sensitivity	1
N-95 Mask	Shoulder Injury	1
N-95 Mask / PPE	COVID	1
N-95 Mask / Ventilator	Death	1
Not Specified	Bell's Palsy	1
Not Specified	Death	133
Not Specified	DVT / Chest Pain / Neurologic Symptoms	1
Not Specified	Not Specified	3
Not Specified	Pancreatitis	1
Not Specified	TIA Stroke	1

Not Specified	Ulcer / Myopathy	1
Not Specified	Weakness / Difficulty Walking	1
Oxygen / Prednisone	Death	1
Oxygen / Remdesivir	Death	1
Permavir / Remdesivir / Steroids	Death	1
Remdesivir	Death	29
Remdesivir	Renal Failure / Pulmonary Embolism / Pneumonia	1
Remdesivir / Tocilizumab	Death	1
Stay At Home Order / Masks / No Elective Surgeries	Attempted Murder / Assault / Damage to Multiple Body Parts	1
Tylenol	Death	1
Ventilator	Collapsed Lung	1
Ventilator	Death	138
Ventilator / Acute Blood Loss / Blood Transfusion	Death	1
Ventilator / Anakinra / Ceftriaxone / Convalescent Plasma / Heparin / Medrol / Steroids / Tocilizumab	Death	1
Ventilator / Antibiotics / Intubation / Sedation	Death	1
Ventilator / Antiviral Medications	Death	2
Ventilator / Antivirals / Convalescent Plasma / Neglect / Pneumonia	Death	1
Ventilator / Azithromycin	Death	10
Ventilator / Azithromycin	Respiratory Failure / Kidney Failure	1
Ventilator / Azithromycin / BiPap / Dialysis / Plaquenil / Tocilizumab	Death	2
Ventilator / Azithromycin / BiPap / Remdesivir	Death	1
Ventilator / Azithromycin / Ceftriaxone	Death	1
Ventilator / Azithromycin / Ceftriaxone / Dialysis / Heparin / Steroids	Death	1
Ventilator / Azithromycin / Ceftriaxone / Dialysis / Heparin / Vancomycin	Death	1
Ventilator / Azithromycin / Convalescent Plasma	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Decadron / Dialysis	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Medrol / Remdesivir	Death	2
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir / Tocilizumab	Death	2

Ventilator / Azithromycin / Convalescent Plasma / Dialysis / Remdesivir / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir	Death	3
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir / Steroids	Death	2
Ventilator / Azithromycin / Convalescent Plasma / Steroids	Death	1
Ventilator / Azithromycin / Decadron / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Azithromycin / Dexamethasone	Death	4
Ventilator / Azithromycin / Dexamethasone / Dialysis	Death	1
Ventilator / Azithromycin / Dexamethasone / Dialysis / Solumedrol	Death	1
Ventilator / Azithromycin / Dexamethasone / Medrol / Remdesivir	Death	1
Ventilator / Azithromycin / Dexamethasone / Methylprednisolone / Remdesivir	Death	2
Ventilator / Azithromycin / Dexamethasone / Remdesivir	Death	6
Ventilator / Azithromycin / Dexamethasone / Remdesivir / Steroids	Death	1
Ventilator / Azithromycin / Dialysis / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Heparin	Death	1
Ventilator / Azithromycin / Ivermectin / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Ivermectin / Remdesivir	Death	1
Ventilator / Azithromycin / Methylprednisolone	Death	1
Ventilator / Azithromycin / Remdesivir	Death	7
Ventilator / Azithromycin / Sedation	Death	1
Ventilator / Azithromycin / Tocilizumab	Death	1
Ventilator / BiPap	Death	2
Ventilator / BiPAP / COVID-19 Medications	Death	1
Ventilator / BiPAP / COVID-19 Medications / Oxygen	Death	1
Ventilator / BiPap / Remdesivir	Death	4
Ventilator / BiPap / Soliris / Remdesivir	Death	1
Ventilator / Ceftriaxone / Remdesivir	Death	1
Ventilator / Convalescent Plasma	Death	6
Ventilator / Convalescent Plasma / Covid-19 Medications	Death	1

Ventilator / Convalescent Plasma / Decadron / Intubation / Lorazepam	Death	1
Ventilator / Convalescent Plasma / Dexamethasone / Remdesivir	Death	1
Ventilator / Convalescent Plasma / Dialysis	Death	1
Ventilator / Convalescent Plasma / Intubation	Death	1
Ventilator / Convalescent Plasma / Remdesivir	Death	6
Ventilator / Convalescent Plasma / Remdesivir / Tocilizumab	Death	1
Ventilator / Covid-19 Medications	Death	666
Ventilator / COVID-19 Medications / COVID-19 Test	Death	1
Ventilator / COVID-19 Medications / Oxygen	Death	1
Ventilator / COVID-19 Vaccine	Death	6
Ventilator / CPAP	Death	1
Ventilator / Dexamethasone	Death	1
Ventilator / Dexamethasone / Dialysis	Death	1
Ventilator / Dexamethasone / Dialysis / Methylprednisolone / Remdesivir	Death	1
Ventilator / Dexamethasone / Remdesivir	Death	3
Ventilator / Dexamethasone / Remdesivir / Tocilizumab	Death	1
Ventilator / Dialysis	Death	1
Ventilator / Endotracheal Tube	Death	1
Ventilator / Hydroxychloroquine	Death	20
Ventilator / Hydroxychloroquine / Antibiotics / Intubation / PIC Line / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Antibiotics / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin	Death	49
Ventilator / Hydroxychloroquine / Azithromycin / Aztreonam / Dexamethasone / Linezolid	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / BiPap / Convalescent Plasma / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / BiPap / Dialysis / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Convalescent Plasma / Doxycycline / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Dialysis / Heparin / Tocilizumab / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Steroids	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Steroids / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Tocilizumab	Death	1

Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / CPAP / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Dialysis	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone / Dialysis / Solu-Medrol / Steroids / Tocilizumab	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis	Death	11
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Heparin / Vasopressin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Solu-Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Solu-Medrol/ Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Steroids	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Steroids / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Tocilizumab	Death	3
Ventilator / Hydroxychloroquine / Azithromycin / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Heparin / Medrol / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Medrol / Vancomycin	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone	Death	5
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone / Remdesivir / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone / Tocilizumab	Death	3
Ventilator / Hydroxychloroquine / Azithromycin / Plaquenil	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Plaquenil / Zithromax	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Remdesivir	Death	19
Ventilator / Hydroxychloroquine / Azithromycin / Remdesivir / Tocilizumab / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Solu-Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Solu-Medrol / Tocilizumab	Death	1

Ventilator / Hydroxychloroquine / Azithromycin / Steroids / Medrol / Ceftriaxone / Heparin / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Steroids / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Tocilizumab	Death	5
Ventilator / Hydroxychloroquine / Ceftriaxone / Convalescent Plasma / Heparin / Medrol / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Ceftriaxone / Heparin	Death	1
Ventilator / Hydroxychloroquine / Ceftriaxone / Heparin / Medrol / Steroids	Death	1
Ventilator / Hydroxychloroquine / Convalescent Plasma	Death	1
Ventilator / Hydroxychloroquine / Convalescent Plasma / Dialysis / Methylprednisolone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Covid-19 Test	Death	1
Ventilator / Hydroxychloroquine / Dexamethasone / Dialysis	Death	1
Ventilator / Hydroxychloroquine / Dexamethasone / Methylprednisolone / Remdesivir / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Dialysis / Heparin / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Dialysis / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Heparin / Medrol / Steroids / Vancomycin / Ventilator	Death	1
Ventilator / Hydroxychloroquine / Medrol	Death	1
Ventilator / Hydroxychloroquine / Methylprednisolone	Death	1
Ventilator / Hydroxychloroquine / Methylprednisolone / Remdesivir / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Remdesivir	Death	7
Ventilator / Hydroxychloroquine / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Steroids / Tocilizumab	Death	2
Ventilator / Hydroxychloroquine / Z-Pac	Death	1
Ventilator / Intubation	Death	3
Ventilator / Lovenox	Death	1
Ventilator / Permavir / Relenza	Death	1
Ventilator / Plaquenil	Death	1
Ventilator / Remdesivir	Death	31
Ventilator / Remdesivir / Convalescent Plasma	Death	3
Ventilator / Remdesivir / Methylprednisolone	Death	1
Ventilator / Remdesivir / Seasonal Flu Vaccine / Midazolam	Death	1
Ventilator / Remdesivir / Steroids	Death	1
Ventilator / Remdesivir / Tocilizumab	Death	1

Ventilator / Tamiflu	Not Specified	1
Ventilator / Tocilizumab	Death	1
Ventilator / Tranquilizer	Death	1
Total COVID-19		**3,158**

Table 2. CICP Claims Compensated (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure, alleged injury and amount of compensation paid for each compensated CICP claim filed between Fiscal Years 2010 through 2021.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury	Compensation Amount
1	H1N1 Vaccine	Guillain-Barrè Syndrome (GBS)	$2,309.94
2	H1N1 Vaccine	Bursitis	$385.00
3	H1N1 Vaccine	Anaphylaxis	$1,885.44
4	Smallpox Vaccine	Myocarditis	$323,035.75
5	H1N1 Vaccine	Anaphylaxis	$2,995.23
6	H1N1 Vaccine	Shoulder Pain	$182.20
7	H1N1 Vaccine	GBS	$1,762,920.56
8	H1N1 Vaccine	GBS	$185,479.52
9	H1N1 Vaccine	GBS	$15,662.07
10	H1N1 Vaccine	GBS	$106,723.54
11	H1N1 Vaccine	GBS	$210.75
12	H1N1 Vaccine	GBS	$2,360.84
13	H1N1 Vaccine	GBS	$2,364.55
14	H1N1 Vaccine	GBS	$3,534.00
15	H1N1 Vaccine	GBS	$6,966.40
16	H1N1 Vaccine	GBS	$553,945.53
17	H1N1 Vaccine	GBS	$7,623.45
18	H1N1 Vaccine	GBS	$2,295,929.61
19	H1N1 Vaccine	GBS	$13,581.93
20	H1N1 Vaccine	GBS	$27,378.82
21	H1N1 Vaccine	GBS	$5,677.77
22	H1N1 Vaccine	GBS	$127,435.39
23	H1N1 Vaccine	GBS	$30.93
24	H1N1 Vaccine	GBS	$3,500.00

25	H1N1 Vaccine	GBS	$38.00
26	H1N1 Vaccine	GBS	$2,316.00
27	H1N1 Vaccine	GBS	$571,635.25
28	H1N1 Vaccine	GBS	$49,759.00
29	H1N1 Vaccine	GBS	$220.00
Total			$6,076,087.47

Table 3. CICP Claims Eligible for Compensation, but No Eligible Reported Losses or Expenses (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was eligible for compensation, but did not have eligible reported losses or expenses.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	H1N1 Vaccine	GBS
2	H1N1 Vaccine	GBS
3	Smallpox Vaccine	Myocarditis
4	H1N1 Vaccine	Anaphylaxis
5	H1N1 Vaccine	GBS
6	Smallpox Vaccine	Serum sickness
7	H1N1 Vaccine	Herpes Zoster Outbreak
8	H1N1 Vaccine	GBS
9	H1N1 Vaccine	GBS
10	H1N1 Vaccine	GBS

Table 4. CICP Claims Denied Compensation Because Required Medical Records Were Not Submitted (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was denied compensation because the requester did not submit any required medical records, which may include not submitting any of the medical records specified in their Authorization for Use or Disclosure of Health Information Form(s) submitted to the Program. When this occurs, CICP staff notify the requester and provide them an opportunity to submit the appropriate medical records. However, if the appropriate medical records are not received, CICP staff are unable to conduct a medical review of the claim. If medical records documenting the alleged injury are received, the claim will proceed to a medical review even if incomplete after the requester has had an opportunity to submit the additional appropriate medical records.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	H1N1 vaccine	Anaphylaxis
2	H1N1 vaccine	Rash (Arm/Shoulder)

Number	Alleged Countermeasure	Alleged Injury
3	H1N1 vaccine	Rash (Upper Torso/Scalp)
4	H1N1 vaccine	Flu Symptoms
5	H1N1 vaccine	Not Specified
6	H1N1 vaccine	Flu Symptoms
7	H1N1 vaccine	Flu Symptoms
8	H1N1 vaccine	Not Specified
9	H1N1 vaccine	Fever/ Difficulty Breathing
10	H1N1 vaccine	Anaphylaxis
11	H1N1 vaccine	Flu Symptoms
12	H1N1 vaccine	Fever / Vomiting / Shortness of Breath
13	H1N1 vaccine	GBS
14	H1N1 vaccine	Neurologic symptoms
15	H1N1 vaccine	Flu Symptoms
16	H1N1 vaccine	Polyarthritis
17	H1N1 vaccine	Gastroenteritis
18	H1N1 vaccine	Allergic Reaction
19	H1N1 vaccine	Miscarriage
20	H1N1 vaccine	Bell’s Palsy
21	H1N1 vaccine	Weakness/ Elevated Blood Pressure
22	H1N1 vaccine	Arm Pain
23	H1N1 vaccine	Hematoma
24	H1N1 vaccine	Rapid Heartbeat / Dizziness
25	H1N1 vaccine	Allergic Reaction
26	H1N1 vaccine	Allergic Reaction
27	H1N1 vaccine	Allergic Reaction
28	H1N1 vaccine	Allergic Reaction
29	H1N1 vaccine	Not Specified
30	H1N1 vaccine	Allergic Reaction
31	H1N1 vaccine	Transverse Myelitis
32	H1N1 vaccine	Allergic Reaction
33	H1N1 vaccine	Allergic Reaction

Number	Alleged Countermeasure	Alleged Injury
34	H1N1 vaccine	GBS
35	H1N1 vaccine	Not Specified
36	H1N1 vaccine	Lymph Node Enlargement
37	H1N1 vaccine	Myalgias
38	H1N1 vaccine	Not Specified
39	H1N1 vaccine	Idiopathic Thrombocytopenic Purpura (ITP)
40	H1N1 vaccine	Anaphylactic Shock
41	H1N1 vaccine	Not Specified
42	H1N1 vaccine	Allergic Reaction
43	H1N1 vaccine	Weakness/ Neurologic Issues
44	H1N1 vaccine	Miscarriage
45	H1N1 vaccine	Rotator Cuff Tear
46	H1N1 vaccine	Numbness/ Swelling
47	H1N1 vaccine	GBS
48	H1N1 vaccine	Edema/ Itching/ Rash/ Skin Lesions/ Weight loss
49	H1N1 vaccine	Autoimmune Encephalopathy
50	H1N1 vaccine	Cyst
51	H1N1 vaccine	Allergic Reaction
52	H1N1 vaccine	Wheezing / Fever
53	H1N1 vaccine	Fever/ Headache/ Severe Pain
54	H1N1 vaccine	Miscarriage
55	H1N1 vaccine	Miscarriage
56	H1N1 vaccine	Allergic Reaction
57	H1N1 vaccine	Bell’s Palsy
58	H1N1 vaccine	GBS
59	H1N1 vaccine	Not Specified
60	H1N1 vaccine	GBS
61	H1N1 vaccine	Obsessive Behavior/ Depression
62	H1N1 vaccine	Not Specified
63	H1N1 vaccine	GBS
64	H1N1 vaccine	Miscarriage

Number	Alleged Countermeasure	Alleged Injury
65	H1N1 vaccine	Diabetes
66	H1N1 vaccine	Allergic Reaction
67	H1N1 vaccine	Neurologic symptoms
68	H1N1 vaccine	Pain at Injection Site
69	H1N1 vaccine	Miscarriage
70	H1N1 vaccine	Fatigue / Spasms
71	H1N1 vaccine + Tamiflu + Relenza	Severe Cough
72	H1N1 vaccine	Pain / Weakness
73	H1N1 vaccine	Severe Cough
74	H1N1 vaccine	Autoimmune Reaction
75	H1N1 vaccine	Not Specified
76	H1N1 vaccine	Allergic Reaction
77	H1N1 vaccine	Headaches / Severe Pain
78	H1N1 vaccine	Headaches / Severe Pain
79	H1N1 vaccine	Peripheral Neuropathy / Paresthesia
80	H1N1 vaccine	Not Specified
81	H1N1 vaccine	Pain / Numbness
82	H1N1 vaccine	Difficulty Breathing
83	H1N1 vaccine	Rash
84	H1N1 vaccine	Not Specified
85	H1N1 vaccine	Miscarriage
86	H1N1 vaccine	Numbness / Pain
87	H1N1 vaccine	Not Specified
88	H1N1 vaccine	Viral Illness
89	H1N1 vaccine	Pneumonia
90	H1N1 vaccine	Not Specified
91	H1N1 vaccine	Hives
92	H1N1 vaccine	Shoulder Severe Pain
93	H1N1 vaccine	Shoulder Pain
94	H1N1 vaccine	Heart Arrhythmia / Syncope/ Seizures/ Stroke

Number	Alleged Countermeasure	Alleged Injury
95	H1N1 vaccine	Not Specified
96	H1N1 vaccine	Polymyositis/ Fibromyalgia
97	H1N1 vaccine	Breathing Issues
98	H1N1 vaccine	Neurologic symptoms
99	H1N1 vaccine	Not Specified
100	H1N1 vaccine	Pain / Nausea / Numbness
101	H1N1 vaccine	GBS
102	H1N1 vaccine	Neuropathy / Dizziness / Fatigue
103	H1N1 vaccine	Not Specified
104	H1N1 vaccine	Not Specified
105	H1N1 vaccine	Not Specified
106	H1N1 vaccine	Not Specified
107	H1N1 vaccine	Rotator Cuff Tear / Tendonitis / Nerve Damage
108	H1N1 vaccine	Flu Symptoms
109	H1N1 vaccine	Not Specified
110	H1N1 vaccine	Death
111	H1N1 vaccine	Paralysis
112	H1N1 vaccine	Immobility / Shoulder pain
113	H1N1 vaccine	Rheumatoid Arthritis / Raynaud's Syndrome
114	H1N1 vaccine	Breathing Issues / Coughing
115	H1N1 vaccine	Pain at Injection Site
116	H1N1 vaccine	Shoulder Pain / Weakness
117	H1N1 vaccine	Pain / Spasms
118	H1N1 vaccine	Numbness / Soreness / Spasms
119	H1N1 vaccine	GBS
120	H1N1 vaccine	Weakness / Numbness
121	Anthrax vaccine	GBS
122	H1N1 vaccine	Paralysis / Numbness / Pain
123	H1N1 vaccine	Paralysis / Pain
124	H1N1 vaccine	Chest Pain

Number	Alleged Countermeasure	Alleged Injury
125	H1N1 vaccine	Bradycardia / Postural Orthostatic Tachycardia Syndrome (POTS) / Hypertension / Headache
126	Smallpox vaccine	GBS
127	Smallpox vaccine	Myocarditis
128	Smallpox vaccine	Pain / Allergic Reaction
129	Anthrax Vaccine	Encephalitis / Seizures
130	H1N1 vaccine	Not Specified
131	Smallpox vaccine	Allergic Reaction
132	Anthrax vaccine	Allergic Reaction / Nervous system Disorder / Thyroid Cancer
133	H1N1 vaccine	GBS / Death
134	Anthrax vaccine	Myocarditis
135	H7N9 Drug Trial	Heart Palpitations

Table 5. CICP Claims Denied Compensation for Not Meeting the Standard of Proof and/or a Covered Injury Was Not Sustained (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. To be eligible for CICP benefits, a requester must show that a covered serious physical injury was sustained as the direct result of the administration or use of a covered countermeasure. **The CICP may only make such determinations based on compelling, reliable, valid, medical and scientific evidence.** A covered injury is a serious physical injury (which, as a general matter, is an injury that warranted hospitalization, whether or not the person was actually hospitalized, or that led to a significant loss of function or disability, whether or not hospitalization was warranted), or death, determined to be:

1. An injury meeting the requirements of a covered countermeasures injury table, unless there is another more likely cause; or
2. An injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes serious aggravation caused by a covered countermeasure of a pre-existing condition.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	H1N1 vaccine	Headaches/ Breathing Difficulty
2	H1N1 vaccine	Eosinophilic Esophagitis
3	H1N1 vaccine	Allergic Reaction
4	H1N1 vaccine	Hearing Loss
5	H1N1 vaccine	Allergic Reaction
6	H1N1 vaccine	Paralysis / Weakness
7	H1N1 vaccine	Allergic Reaction
8	H1N1 vaccine	ITP
9	H1N1 vaccine	Flu Symptoms

Number	Alleged Countermeasure	Alleged Injury
10	H1N1 vaccine	Flu Symptoms
11	H1N1 vaccine	Abdominal Pain
12	H1N1 vaccine	Acute Cardiopulmonary Arrest
13	H1N1 vaccine	Neuropathy
14	H1N1 vaccine	Transverse Myelitis
15	H1N1 vaccine	Flu Symptoms
16	H1N1 vaccine	Bronchitis
17	H1N1 vaccine	Asthma
18	H1N1 vaccine	Transverse Myelitis
19	H1N1 vaccine	Connective Tissue Disease
20	H1N1 vaccine	Premature Labor
21	H1N1 vaccine	Migraine Headaches
22	H1N1 vaccine	Flu Symptoms
23	H1N1 vaccine	Neuropathy
24	H1N1 vaccine	Fibromyalgia / Groves Disease
25	H1N1 vaccine	Allergic Hepatitis
26	H1N1 vaccine	Allergic Reaction
27	H1N1 vaccine	A-Fib / Difficulty Breathing
28	H1N1 vaccine	Pain / Numbness
29	H1N1 vaccine	GBS
30	H1N1 vaccine	Neuropathy
31	H1N1 vaccine	Acute Disseminated Encephalomyelitis (ADEM)
32	H1N1 vaccine	GBS
33	H1N1 vaccine	GBS
34	H1N1 vaccine	Hyperthyroidism
35	H1N1 vaccine	Upper Respiratory Infection
36	H1N1 vaccine	Paresthesias
37	H1N1 vaccine	GBS
38	H1N1 vaccine	Allergic Reaction
39	H1N1 vaccine	Movement Disorder
40	H1N1 vaccine	Migraine Headaches

Number	Alleged Countermeasure	Alleged Injury
41	H1N1 vaccine	Death
42	H1N1 vaccine	Muscle Strain
43	H1N1 vaccine	Bell's Palsy
44	H1N1 vaccine	Death
45	H1N1 vaccine	Miscarriage
46	H1N1 vaccine	Headaches / Shortness of Breath / Miscarriage
47	H1N1 vaccine	Neurologic symptoms
48	H1N1 vaccine	Not Specified
49	H1N1 vaccine	GBS
50	H1N1 vaccine	GBS
51	H1N1 vaccine	Optic Neuritis
52	H1N1 vaccine	GBS / Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
53	H1N1 vaccine	Allergic Reaction
54	H1N1 vaccine	Miscarriage
55	H1N1 vaccine	Neuropathy
56	H1N1 vaccine	Anaphylactic Shock
57	H1N1 vaccine	Stroke
58	H1N1 vaccine	Weakness / Heart Palpitations
59	H1N1 vaccine	Abdominal Pain
60	H1N1 vaccine	Bronchitis / Pneumonia / Shoulder Pain/ Weakness
61	H1N1 vaccine	Seizures / Fatigue
62	H1N1 vaccine	CIDP
63	H1N1 vaccine	Idiopathic Polyneuropathy
64	H1N1 vaccine	Henoch Schonlein Purpura (HSP)
65	H1N1 vaccine	Ocular Migraine
66	H1N1 vaccine	Allergic Reaction
67	H1N1 vaccine	Miscarriage
68	H1N1 vaccine	Myocarditis
69	H1N1 vaccine	Miscarriage
70	H1N1 vaccine	Rash
71	H1N1 vaccine	Pneumonia

Number	Alleged Countermeasure	Alleged Injury
72	H1N1 vaccine	Rash / Hives
73	H1N1 vaccine	Rheumatoid Arthritis / Fatigue / Pain/ Headaches
74	H1N1 vaccine	GBS Symptoms / Nausea
75	H1N1 vaccine	Small Fiber Neuropathy
76	H1N1 vaccine	Small Fiber Neuropathy
77	H1N1 vaccine	Weakness / Low Blood Pressure / Rapid Heartbeat
78	H1N1 vaccine	Seizures
79	H1N1 vaccine	GBS
80	H1N1 vaccine	Hives / Brain Swelling
81	H1N1 vaccine	GBS
82	H1N1 vaccine	Nerve Damage
83	H1N1 vaccine	Peripheral neuropathy
84	H1N1 vaccine	Gastroparesis
85	H1N1 vaccine	Chronic Pain
86	H1N1 vaccine	Fever / Pain / Weakness / Swelling/ Fatigue
87	H1N1 vaccine	Death
88	H1N1 vaccine	Vertigo
89	H1N1 vaccine	Adhesive Capsulitis
90	H1N1 vaccine	Flu
91	H1N1 vaccine	Allergic Reaction
92	H1N1 vaccine	GBS
93	H1N1 vaccine	Miscarriage
94	H1N1 vaccine	Tachycardia
95	H1N1 vaccine	GBS
96	H1N1 vaccine	Weakness/ Swelling
97	H1N1 vaccine	GBS Symptoms
98	H1N1 vaccine	Damage to Auto-Immune System
99	H1N1 vaccine	Pharyngitis / Tachycardia
100	H1N1 vaccine	CIDP
101	H1N1 vaccine	Muscle Pain
102	H1N1 vaccine	Transverse Myelitis

Number	Alleged Countermeasure	Alleged Injury
103	H1N1 vaccine	Bell's Palsy
104	H1N1 vaccine	Pneumonia
105	H1N1 vaccine	Headaches / Paresthesias
106	H1N1 vaccine	Dizziness / Weakness
107	H1N1 vaccine	Numbness / Hypertension/ Brachial Neuritis
108	H1N1 vaccine	CIDP
109	H1N1 vaccine	Transverse Myelitis
110	H1N1 vaccine	Anaphylaxis / Pneumonia
111	H1N1 vaccine	ITP
112	H1N1 vaccine	Multiple Sclerosis
113	H1N1 vaccine	Asthma / Pneumonia
114	H1N1 vaccine	Serum Sickness
115	H1N1 vaccine	Pain / Weakness
116	H1N1 vaccine	Tingling
117	H1N1 vaccine	Indigestion
118	H1N1 vaccine	Brachial Plexus
119	H1N1 vaccine	Eye Problems
120	H1N1 vaccine	GBS
121	H1N1 vaccine	Fibromyalgia
122	H1N1 vaccine	Wheezing / Fatigue / Weakness
123	H1N1 vaccine	Paralysis
124	H1N1 vaccine	Conversion Disorder
125	H1N1 vaccine	Flu-like Symptoms
126	H1N1 vaccine	Brain Lesions
127	H1N1 vaccine	CIDP
128	H1N1 vaccine	Polyarthritis
129	H1N1 vaccine	Shoulder Pain/ Ovarian Cyst
130	H1N1 vaccine	Neuropathy
131	H1N1 vaccine	Delusions
132	H1N1 vaccine	Pain / Nausea / Weakness / Numbness / Fatigue
133	H1N1 vaccine	Myocarditis

Number	Alleged Countermeasure	Alleged Injury
134	H1N1 vaccine	Vasculitis / Renal Failure
135	H1N1 vaccine	GBS
136	H1N1 vaccine	GBS
137	H1N1 vaccine	GBS
138	H1N1 vaccine	Boil
139	H1N1 vaccine	CIDP
140	H1N1 vaccine	Acute Disseminated Encephalomyelitis (ADEM)
141	H1N1 vaccine	Encephalitis / Seizures
142	H1N1 vaccine	Tinnitus / Hearing Loss
143	H1N1 vaccine	Reflex Sympathetic Dystrophy, Meningitis
144	H1N1 vaccine	Dyspnea / Severe Pain
145	H1N1 vaccine	Transverse Myelitis
146	H1N1 vaccine	Myalgias
147	H1N1 vaccine	Anaphylactic Shock
148	H1N1 vaccine	Fever / Loss of Consciousness
149	H1N1 vaccine	Weakness / Severe Pain / Migraine
150	H1N1 vaccine	GBS
151	H1N1 vaccine	Weakness / Neurologic Issues
152	H1N1 vaccine	GBS
153	H1N1 vaccine	GBS
154	H1N1 vaccine	GBS
155	H1N1 vaccine	Acute Kidney Injury
156	H1N1 vaccine	Chronic Fatigue Syndrome
157	H1N1 vaccine	Neurologic symptoms
158	H1N1 vaccine	Death
159	H1N1 vaccine	Death
160	H1N1 vaccine	Serum Sickness
161	H1N1 vaccine	Weakness / Numbness / Pain
162	H1N1 vaccine	High Blood Pressure
163	H1N1 Vaccine	Hearing Loss
164	H1N1 vaccine	Seizures / Encephalopathy

Number	Alleged Countermeasure	Alleged Injury
165	H1N1 vaccine	Numbness / Pain / Tremors/ Nausea
166	H1N1 vaccine	Speech Loss
167	H1N1 vaccine	Parethesias
168	H1N1 vaccine	Numbness / Weakness / Fatigue
169	H1N1 vaccine	Weakness / Swelling
170	H1N1 vaccine	Hearing Loss
171	H1N1 vaccine	Severe Pain
172	H1N1 vaccine	Rash / Swelling / Fever
173	H1N1 vaccine	Swelling/ Miscarriage / Rash/ Swollen Lymph Nodes
174	H1N1 vaccine	Allergic Reaction
175	H1N1 vaccine	Henoch Schonlein Purpura (HSP)
176	H1N1 vaccine	Autonomic Dysfunction
177	H1N1 vaccine	Bell's Palsy
178	H1N1 vaccine	Arm Pain / Edema / Blurry Vision
179	H1N1 vaccine	Brain Elisions / Weakness / Paralysis
180	H1N1 vaccine	Acquired Hemophilia A
181	H1N1 vaccine	Acute Transverse Myelitis
182	H1N1 vaccine	Seizures
183	H1N1 vaccine	Seizures
184	H1N1 vaccine	GBS
185	H1N1 vaccine	GBS
186	H1N1 vaccine	Seizures
187	H1N1 vaccine	GBS
188	H1N1 vaccine	GBS
189	H1N1 vaccine	Headaches / Tremors / Nausea / Dizziness
190	H1N1 vaccine	Serum Sickness
191	H1N1 vaccine	Death
192	H1N1 vaccine	Encephalopathy
193	H1N1 vaccine	Pain
194	H1N1 vaccine	Seizures
195	H1N1 vaccine	Not Specified

Number	Alleged Countermeasure	Alleged Injury
196	H1N1 vaccine	Fever
197	H1N1 vaccine	GBS
198	H1N1 vaccine	GBS
199	H1N1 vaccine	Brachial Neuritis
200	H1N1 vaccine	Bronchitis
201	H1N1 vaccine	Cellulitis
202	H1N1 vaccine	Rheumatoid Arthritis
203	H1N1 vaccine	Interstitial Cystitis / Celiac Sprue
204	H1N1 vaccine	CIDP
205	H1N1 vaccine	Fibromyalgia / Lyme Disease
206	H1N1 vaccine	GBS
207	H1N1 vaccine	Bell's Palsy
208	H1N1 vaccine	Rash
209	H1N1 vaccine	GBS
210	H1N1 vaccine	Myositis
211	H1N1 vaccine	Leg Pain / Weakness / Anxiety
212	H1N1 vaccine	CIDP
213	H1N1 vaccine	GBS
214	Anthrax vaccine	Undifferentiated Connective Tissue Disease
215	Anthrax vaccine	Headaches
216	H5N1 vaccine	Esophagitis
217	H1N1 vaccine	Seizures / Brain Damage
218	Anthrax vaccine	Allergic Reaction
219	Smallpox vaccine / Anthrax vaccine	Hypertension
220	Anthrax vaccine	Serum Sickness
221	Smallpox vaccine	Death
222	Smallpox vaccine	Pain / Itching
223	Smallpox vaccine	Hand Tingling, Headache, Chest Pain, Drowsiness, Disorientation
224	Anthrax vaccine	Myalgia

Alleged COVID-19 Countermeasures

Number	Alleged Countermeasure	Alleged Injury

Number	Alleged Countermeasure	Alleged Injury
225	Ventilator	Death
226	COVID-19 Vaccine	Swelling of the Tongue and Throat, Difficulty Speaking and Swallowing and Dizziness
227	COVID-19 Vaccine	SIRVA

Table 6. CICP Ineligible Claims due to Missing the Filing Deadline (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was ineligible because the Request for Benefits (claim) was not filed within the 1-year filing deadline. The claim must be filed within 1 year after the date of the administration or use of the covered countermeasure alleged to have caused the injury or within 1 year after the effective date of the establishment of, or amendment to, a countermeasure injury table.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	Anthrax vaccine	Epilepsy/ Seizures
2	Anthrax vaccine	Pain/ Blisters
3	H1N1 vaccine	Anxiety Attack
4	H1N1 vaccine	Bilateral Brachial plexus
5	H1N1 vaccine	Bradycardia
6	H1N1 vaccine	CIDP
7	H1N1 vaccine	Fatigue / Fibromyalgia / Brachial Neuritis
8	H1N1 vaccine	GBS
9	H1N1 vaccine	GBS
10	H1N1 vaccine	Miscarriage
11	H1N1 vaccine	Myopericarditis
12	H1N1 vaccine	Narcolepsy
13	H1N1 vaccine	Neurologic symptoms
14	H1N1 vaccine	Not Specified
15	H1N1 Vaccine	Numbness / Amputation
16	H1N1 vaccine	Numbness / Metallic Taste
17	H1N1 vaccine	Optic Neuritis
18	H1N1 vaccine	Pain / Weakness
19	H1N1 vaccine	Paralysis
20	H1N1 vaccine	Paralysis / Severe Pain
21	H1N1 vaccine	Pericarditis
22	H1N1 vaccine	Pneumonia / Edema/ Paralysis/ Confusion

Number	Alleged Countermeasure	Alleged Injury
23	H1N1 vaccine	Postural Orthostatic Tachycardia Syndrome (POTS)
24	H1N1 vaccine	Rash
25	H1N1 vaccine	Rheumatoid Arthritis
26	H1N1 vaccine	Seizures
27	H1N1 vaccine	Severe Arm Pain
28	H1N1 vaccine	Severe Pain
29	H1N1 vaccine	Shoulder Pain
30	H1N1 vaccine	Vision Problems / Paralysis
31	H1N1 vaccine	Weakness / Severe Pain
32	H1N1 vaccine	Weakness / Neurologic Issues
33	H1N1 vaccine	Vasculitis / Tendonitis / Polymyalgia Rheumatica
34	H1N1 vaccine	Transverse Myelitis
35	Smallpox vaccine	Pericarditis
36	Smallpox vaccine	Not Specified
37	Smallpox vaccine	Heart Swelling / High Blood Pressure/ Paralysis
38	Smallpox Vaccine, Anthrax Vaccine	Severe Ulcerative Colitis

Table 7. Ineligible Claims for Products Not Covered by the CICP (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was ineligible because the Request for Benefits (claim) alleged an injury from a product that the CICP does not cover.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	1976 H1N1 vaccine	GBS
2	1976 H1N1 vaccine	GBS
3	Pre-Prep Act Anthrax vaccine	Fatigue/ Fibromyalgia/ Depression/ Lesions
4	Pre-Prep Act Anthrax vaccine	Migraine Headaches
5	Pre-Prep Act Anthrax vaccine	Migraine Headaches
6	Pre-Prep Act Anthrax vaccine	Migraine Headaches / Pain / Diarrhea
7	Pre-Prep Act Anthrax vaccine	Nerve Disorder / Sleep Disorder
8	Pre-Prep Act Anthrax vaccine	Neuropathy / Central Nervous System Demyelinating Disease / Inflammatory Joint Disease / Fatigue
9	Pre-Prep Act Anthrax vaccine	Not Specified

Number	Alleged Countermeasure	Alleged Injury
10	Pre-Prep Act Anthrax vaccine	Diarrhea / Fatigue / Asthma
11	Pre-Prep Act Anthrax vaccine	Myofacial Pain Syndrome / SLE Lupus / Scoliosis / SI Joint Dysfunction / IBS Syndrome / Night Sweats / Psychosis
12	DTAP, MMR vaccines	Minimal Change Disease
13	DTAP, Polio, and Haemoplilus Influenzae B vaccines	Seizures / Infantile Spasms / Delayed Development
14	Human Papillomavirus (HPV) Vaccine	Enlarged Lymph Nodes/ Spleen and Liver
15	HPV vaccine	Neurologic Symptoms
16	Influenza / Pneumococcal Vaccines	Allergic Reaction
17	Japanese Encephalitis vaccine	Weakness/ Neurologic Issues
18	Meningococcal vaccine	Double Vision
19	Meningococcal vaccine	Shoulder Pain
20	Pneumococcal Vaccine	Pain/ Fever/ Inflammation
21	Pneumococcal vaccine	Fainting
22	Pneumococcal vaccine	Not Specified
23	Seasonal Flu vaccine	Arm Pain
24	Seasonal Flu vaccine	Arm Swelling
25	Seasonal Flu vaccine	Bipolar Disorder/ Depression
26	Seasonal Flu vaccine	Birth Defects
27	Seasonal Flu vaccine	Calcified Tendons/ Arthritis symptoms
28	Seasonal Flu vaccine	CIDP
29	Seasonal Flu vaccine	Death
30	Seasonal Flu vaccine	Flu-like Symptoms
31	Seasonal Flu vaccine	Flu-like Symptoms
32	Seasonal Flu vaccine	Frozen Shoulder Syndrome
33	Seasonal Flu vaccine	GBS
34	Seasonal Flu vaccine	GBS
35	Seasonal Flu vaccine	Headache / Tremors / Fever
36	Seasonal Flu vaccine	Laryngitis
37	Seasonal Flu vaccine	Neurologic symptoms
38	Seasonal Flu vaccine	Not Specified
39	Seasonal Flu vaccine	Numbness / Weakness / Headaches/ Double Vision

Number	Alleged Countermeasure	Alleged Injury
40	Seasonal Flu vaccine	Paralysis
41	Seasonal Flu vaccine	Paralysis / Pain
42	Seasonal Flu vaccine	Paralysis / Pain
43	Seasonal Flu vaccine	Paresthesia / Weakness / Tremors
44	Seasonal Flu vaccine	Severe Arm Pain
45	Seasonal Flu vaccine	Shoulder Pain
46	Seasonal Flu vaccine	Shoulder Pain
47	Seasonal Flu vaccine	Stevens Johnson Syndrome
48	Seasonal Flu vaccine	GBS
49	Shingles vaccine	Immobility / Fibromyalgia / Depression
50	Shingrix vaccine	Pain
51	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Boils / Stroke / High Blood Pressure / Arthritis
52	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Not Specified
53	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Organic Brain Syndrome / Neuropathy
54	Tetanus, Diphtheria, Acellular Pertussis (TDAP) Vaccine	Arm Pain

Table 8. CICP Ineligible Claims Due to Not Alleging Any Countermeasure Administration or Use (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that is ineligible because the Request for Benefits did not allege the administration or use of any countermeasure.

Number	Alleged Countermeasure	Alleged Injury
1	Not Specified	Weakness/ Neurologic Issues

Date Last Reviewed: October 2021

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE**, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection.

Primary Series:

Each primary series dose of the Moderna COVID-19 Vaccine is **0.5 mL**.

The Moderna COVID-19 Vaccine is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 18 years of age or older.

A third primary series dose of the Moderna COVID-19 Vaccine (0.5 mL) at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:

The booster dose of the Moderna COVID-19 Vaccine is **0.25 mL**.

A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals 18 years of age or older.

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have

been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2° to 8°C (36° to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (36° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (36° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and

transported at 2° to 8°C (36° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (36° to 46°F) until use.

Dosing and Schedule

Primary Series:
Each primary series dose of the Moderna COVID-19 Vaccine is **0.5 mL**.

The Moderna COVID-19 Vaccine is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 18 years of age or older.

A third primary series dose of the Moderna COVID-19 Vaccine (0.5 mL) at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:
The booster dose of the Moderna COVID-19 Vaccine is **0.25 mL**.

A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals 18 years of age or older.

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Multiple-dose Vials Containing	Thaw in Refrigerator	Thaw at Room Temperature
5.5 mL	Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
7.5 mL	Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
    - A multiple-dose vial containing 5.5 mL
    - A multiple-dose vial containing 7.5 mL
- Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.
- When extracting only primary series doses, depending on the syringes and needles used, a maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL.
- When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.
- Irrespective of the type of syringe and needle:
    - Each primary series dose must contain 0.5 mL of vaccine.
    - Each booster dose must contain 0.25 mL of vaccine.
    - If the vial stopper has been punctured 20 times, discard the vial and contents.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

Administration
Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL for a primary series dose or 0.25 mL for a booster dose.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

WARNINGS

Management of Acute Allergic Reactions
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis
Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

Some, but not all, observational analyses of postmarketing data suggest that there may be an increased risk of myocarditis and pericarditis in males under 40 years of age following the second dose of the Moderna COVID-19 Vaccine relative to other authorized or approved mRNA COVID-19 vaccines. Although postmarketing data following a booster dose of mRNA vaccines are limited, available evidence suggests a lower myocarditis risk following a booster dose relative to the risk following the primary series second dose.

The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials
Adverse reactions reported in clinical trials following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, erythema at the injection site, and rash. *(See Full EUA Prescribing Information)*

Adverse Reactions in Post-Authorization Experience
Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES
There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS
As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving each dose of the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events* (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
   - cases of COVID-19 that result in hospitalization or death.

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information

about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

*Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES
Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. There may be clinical trials or availability under EUA of other

COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization, visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP

regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Dec/9/2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA)
PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Multiple-dose Vials Containing	Thaw in Refrigerator	Thaw at Room Temperature
5.5 mL	Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
7.5 mL	Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
    - A multiple-dose vial containing 5.5 mL
    - A multiple-dose vial containing 7.5 mL
- Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.
- When extracting only primary series doses, depending on the syringes and needles used, a maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL.
- When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.
- Irrespective of the type of syringe and needle:
    - Each primary series dose must contain 0.5 mL of vaccine.
    - Each booster dose must contain 0.25 mL of vaccine.
    - If the vial stopper has been punctured 20 times, discard the vial and contents.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL for a primary series dose or 0.25 mL for a booster dose.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

Primary Series:
Each primary series dose of the Moderna COVID-19 Vaccine is **0.5 mL**.

The Moderna COVID-19 Vaccine is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 18 years of age or older.

A third primary series dose of the Moderna COVID-19 Vaccine (0.5 mL) at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:
The booster dose of the Moderna COVID-19 Vaccine is **0.25 mL**.

A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals 18 years of age or older.

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection.

- Each primary series dose is 0.5 mL.
- The booster dose is 0.25 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

Some, but not all, observational analyses of postmarketing data suggest that there may be an increased risk of myocarditis and pericarditis in males under 40 years of age following the second dose of the Moderna COVID-19 Vaccine relative to other authorized or approved mRNA COVID-19 vaccines. Although postmarketing data following a booster dose of mRNA vaccines are limited, available evidence suggests a lower myocarditis risk following a booster dose relative to the risk following the primary series second dose.

The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may

have a diminished response to the Moderna COVID-19 Vaccine.

5.5 Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In a clinical study, the adverse reactions in participants 18 years of age and older following administration of the primary series included pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

In a clinical study, the adverse reactions in participants 18 years of age and older following administration of a booster dose included pain at the injection site (83.8%), fatigue (58.7%), headache (55.1%), myalgia (49.1%), arthralgia (41.3%), chills (35.3%), axillary swelling/tenderness (20.4%), nausea/vomiting (11.4%), fever (6.6%), swelling at the injection site (5.4%), erythema at the injection site (4.8%), and rash (1.8%).

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427). In a fourth clinical trial (NCT04885907), 60 solid organ transplant recipients received a third dose of Moderna COVID-19 Vaccine.

Two-Dose Primary Series

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized,

placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose (0.5 mL) of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (Study 1, NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Local and systemic adverse reactions and use of antipyretic medication were solicited in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Events that persisted for more than 7 days were followed until resolution. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo[a]**	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade 3[f]	219 (1.9)	553 (5.0)	162 (1.4)	129 (1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
[h] Grade 3 nausea/vomiting: Defined as prevents daily activity; requires outpatient intravenous hydration.
[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.
[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo[a]**	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting, Grade 3[g]	4 (0.1)	10 (0.3)	4 (0.1)	3 (<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[g] Grade 3 nausea/vomiting: Defined as prevents daily activity; requires outpatient intravenous hydration.

[h] Grade 4 nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.

[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than after Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported

by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Solid Organ Transplant Recipients

From an independent study (NCT04885907), in 60 participants who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years) who received a third vaccine dose (0.5 mL), the adverse event profile was similar to that after the second dose and no Grade 3 or Grade 4 events were reported.

Booster Dose Following a Primary Series of Moderna COVID-19 Vaccine

Study 2 is an ongoing Phase 2, randomized, observer-blind, placebo-controlled, dose-confirmation study to evaluate the safety, reactogenicity, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older (NCT04405076). In this study, 198 participants received two doses (0.5 mL 1 month apart) of the Moderna COVID-19 Vaccine primary series. In an open label-phase, 171 of those participants received a single booster dose (0.25 mL) at least 6 months (range of 5.8 to 8.5 months) after receiving the second dose of the primary series. Safety monitoring after the booster dose was the same as that described for Study 1 participants who received the primary series.

Among the 171 booster dose recipients, the median age was 55 years (range 18-87), 39.2% were male and 60.8% were female, 95.9% were White, 5.8% were Hispanic or Latino, 2.9% were Black or African American, 0.6% were Asian, and 0.6% were American Indian or Alaska Native. Following the booster dose, the median follow-up time was 5.7 months (range of 3.1 to 6.4 months).

Solicited Adverse Reactions

Tables 3 and 4 present the frequency and severity of reported solicited local and systemic adverse reactions among Study 2 Moderna COVID-19 Vaccine booster dose recipients 18 to <65 years of age and ≥65 years of age, respectively, within 7 days of a booster vaccination.

Table 3: Number and Percentage of Study 2 Participants 18-64 Years of Age With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After the Booster Dose or After the Second Dose of Primary Series (Solicited Safety Set)

	Study 2 Second Dose of Primary Series (N=155) n (%)	**Study 2 Booster Dose** (N=129) n (%)
Local Adverse Reactions		
Pain	137 (88.4)	111 (86.0)
Pain, Grade 3[a]	1 (0.6)	4 (3.1)

	Study 2 Second Dose of Primary Series (N=155) n (%)	**Study 2 Booster Dose** (N=129) n (%)
Axillary swelling/tenderness	18 (11.6)	32 (24.8)
Axillary swelling/tenderness, Grade 3[a]	0 (0)	1 (0.8)
Swelling (hardness) ≥25 mm	16 (10.3)	8 (6.2)
Erythema (redness) ≥25 mm	12 (7.7)	7 (5.4)
Erythema (redness), Grade 3[b]	2 (1.3)	1 (0.8)
Systemic Adverse Reactions		
Fatigue	105 (67.7)	80 (62.0)
Fatigue, Grade 3[c]	16 (10.3)	4 (3.1)
Headache	87 (56.1)	76 (58.9)
Headache, Grade 3[d]	8 (5.2)	1 (0.8)
Myalgia	89 (57.4)	64 (49.6)
Myalgia, Grade 3[c]	15 (9.7)	4 (3.1)
Arthralgia	66 (42.6)	54 (41.9)
Arthralgia, Grade 3[c]	8 (5.2)	4 (3.1)
Chills	71 (45.8)	52 (40.3)
Chills, Grade 3[e]	1 (0.6)	0 (0)
Nausea/vomiting	36 (23.2)	16 (12.4)
Fever	24 (15.5)	9 (7.0)
Fever, Grade 3[f]	3 (1.9)	2 (1.6)
Rash	5 (3.2)	3 (2.3)
Use of antipyretic or pain medication	86 (55.5)	64 (49.6)

***** 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[b] Grade 3 erythema: Defined as >100 mm / >10 cm.

[c] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[d] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[e] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[f] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

Table 4: Number and Percentage of Study 2 Participants ≥65 Years of Age With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After the Booster Dose or After the Second Dose of Primary Series (Solicited Safety Set)

	Study 2 Second Dose of Primary Series (N=43) n (%)	**Study 2 Booster Dose** (N=38) n (%)
Local Adverse Reactions		
Pain	32 (74.4)	29 (76.3)
Pain, Grade 3[a]	0 (0.0)	2 (5.3)
Axillary swelling/tenderness	2 (4.7)	2 (5.3)
Swelling (hardness) ≥25 mm	5 (11.6)	1 (2.6)
Swelling (hardness), Grade 3[b]	1 (2.3)	1 (2.6)
Erythema (redness) ≥25 mm	3 (7.0)	1 (2.6)

	Study 2 Second Dose of Primary Series (N=43) n (%)	**Study 2 Booster Dose** (N=38) n (%)
Erythema (redness), Grade 3[b]	3 (7.0)	0 (0.0)
Systemic Adverse Reactions		
Fatigue	23 (53.5)	18 (47.4)
Fatigue, Grade 3[c]	2 (4.7)	3 (7.9)
Myalgia	15 (34.9)	18 (47.4)
Myalgia, Grade 3[c]	0 (0)	1 (2.6)
Headache	17 (39.5)	16 (42.1)
Headache, Grade 3[d]	1 (2.3)	1 (2.6)
Arthralgia	11 (25.6)	15 (39.5)
Arthralgia, Grade 3[c]	0 (0)	1 (2.6)
Chills	7 (16.3)	7 (18.4)
Nausea/vomiting	5 (11.6)	3 (7.9)
Fever	2 (4.7)	2 (5.4)
Fever, Grade 3[e]	1 (2.3)	0 (0)
Rash	1 (2.3)	0 (0.0)
Use of antipyretic or pain medication	11 (25.6)	11 (28.9)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).
[a] Grade 3 pain: Defined as any use of prescription pain reliever; prevents daily activity.
[b] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.
[c] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
[d] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[e] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

In participants who received a booster dose, the median duration of solicited local and systemic adverse reactions was 2 to 3 days.

Unsolicited Adverse Events

Overall, the 171 participants who received a booster dose had a median follow-up time of 5.7 months after the booster dose to the cut-off date (August 16, 2021). Through the cut-off date, there were no unsolicited adverse events not already captured as solicited local and systemic reactions that were considered causally related to the Moderna COVID-19 Vaccine.

Serious Adverse Events

Of the 171 participants who received a booster dose of Moderna COVID-19 Vaccine, there were no serious adverse events reported from the booster dose through 28 days after the booster dose. Through the cut-off date of August 16, 2021, there were no serious adverse events following the booster dose considered causally related to the Moderna COVID-19 Vaccine.

Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine

The safety of a Moderna COVID-19 Vaccine (0.25 mL) booster dose in individuals who completed primary vaccination with another authorized or approved COVID-19 Vaccine (heterologous booster dose) is inferred from the safety of a Moderna COVID-19 Vaccine (0.25 mL) booster dose administered following completion of a Moderna COVID-19 Vaccine primary series (homologous booster dose) and from data from an independent Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose (0.5 mL) of the Moderna COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine (0.5 mL), Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported following the Moderna COVID-19 Vaccine heterologous booster dose (0.5 mL) did not identify any new safety concerns, as compared with adverse reactions reported following Moderna COVID-19 Vaccine primary series doses or homologous booster dose (0.25 mL).

6.2 Post-Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Moderna COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Immune System Disorders: anaphylaxis
Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write “Moderna COVID-19 Vaccine EUA” as the first line
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:

a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients

included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study (Study 1) of primary series dosing (0.5 mL), 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age *[see Clinical Trial Results and Supporting Data for EUA (18)]*. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants *[*see *Overall Safety Summary (6.1)]*.

In an ongoing Phase 2 clinical study (Study 2) of a single booster dose (0.25 mL), 22.2% (n=38) of participants were 65 years of age and older. This study did not include sufficient numbers of participants 65 years of age and older to determine whether they respond differently than younger participants. Some local and systemic adverse reactions were reported in a lower proportion of participants 65 years of age and older compared to participants 18 through 64 years of age *[see Overall Safety Summary (6.1)]*.

11.5 Use in Immunocompromised

In an independent study, safety and effectiveness of a third 0.5 mL primary series dose of the Moderna COVID-19 Vaccine have been evaluated in participants who received solid organ transplants *[see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.2)]*. The administration of a third primary series vaccine dose appears to be only moderately effective in increasing antibody titers. Patients should be counseled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated, as appropriate for their health status.

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection.

Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus. Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose. Each 0.25 mL dose of Moderna COVID-19 Vaccine contains half of these ingredients.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy of Two-Dose Primary Series

Study 1 is an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart.

Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (0.5 mL at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38ºC / ≥100.4°F), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS- CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow-up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 5: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 6.

Table 6: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

18.2 Immunogenicity in Solid Organ Transplant Recipients

An independent randomized-controlled study has been conducted in 120 participants who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years). A third 0.5 mL primary series dose of the Moderna COVID-19 Vaccine was administered to 60 participants approximately 2 months after they had received a second dose; saline placebo was given to 60 individuals for comparison. Significant increases in levels of SARS-CoV-2 antibodies occurred four weeks after the third dose in 55.0% of participants in the Moderna COVID-19 Vaccine group (33 of 60) and 17.5% of participants in the placebo group (10 of 57).

18.3 Immunogenicity of a Booster Dose Following a Moderna COVID-19 Vaccine Primary Series

Effectiveness of a booster dose of the Moderna COVID-19 Vaccine was based on assessment of neutralizing antibody titers (ID50) against a pseudovirus expressing the SARS-CoV-2 Spike protein from a USA_WA1/2020 isolate carrying the D614G mutation. Immunogenicity analyses compared the ID50 following the booster dose to the ID50 following the primary series.

In an open-label phase of Study 2, participants 18 years of age and older received a single booster dose (0.25 mL) at least 6 months after completion of the primary series (two doses of 0.5 mL 1 month apart). The primary immunogenicity analysis population included 149 booster dose participants in Study 2 (including one individual who had only received a single dose of the primary series) and a random subset of 1,055 participants from Study 1 who received two doses (0.5 mL 1 month apart) of Moderna COVID-19 Vaccine. Study 1 and 2 participants included in the analysis population had no serologic or virologic evidence of SARS-CoV-2 infection prior to the first primary series dose and prior to the booster dose, respectively. Among participants assessed for immunogenicity, 60.4% were female, 6.7% were Hispanic or Latino; 95.3% were White, 3.4% were Black or African American, 0.7% were Asian, and 0.7% were American Indian or Alaskan Native; 9.4% were obese (body mass index ≥30 kg/m^2). The median age of Study 2 participants was 56 years of age (range 18-82) and 24.8% of participants were 65 years of age and older. Study 2 participants included in the primary immunogenicity analysis population did not have pre-existing medical conditions that would place them at risk of severe COVID-19. Study 1 participants included in the primary immunogenicity analysis population were a stratified random sample which reflected the overall primary efficacy analysis population with regards to demographics and pre-existing medical conditions with a higher percentage of those ≥65 years of age (33.6%), with risk factors for severe COVID-19 (39.4%), and communities of color (53.5%).

Immunogenicity analyses included an assessment of ID50 geometric mean titer (GMT) ratio and difference in seroresponse rates. The analysis of the GMT ratio of ID50 following the booster dose compared to the primary series met the immunobridging criteria for a booster response. Seroresponse for a participant was defined as achieving a ≥4-fold rise in ID50 from baseline (before the booster dose in Study 2 and before the first dose of the primary series in Study 1). The lower limit of the 2-sided 95% CI for the difference in seroresponse rates between Study 1 and Study 2 was -16.7%, which did not meet the immunobridging criterion for a booster response (lower limit of 2-sided 95% CI for the percentage difference of ≥ -10%). These analyses are summarized in Tables 7 and 8.

Table 7: Neutralizing Antibody Geometric Mean Titers (ID50) Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days After a Booster Dose in Study 2 vs 28 Days After Completion of the Primary Series in Study 1, Participants ≥18 Years of Age, Per-Protocol Immunogenicity Set*

Study 2 Booster Dose N[a]=149 GMT[b] (95% CI)	Study 1 Primary Series N[a]=1053 GMT[b] (95% CI)	GMT Ratio (Study 2/Study 1)	Met Success Criteria[c]
1802 (1548, 2099)	1027 (968, 1089)	1.8 (1.5, 2.1)	Lower limit of 95% CI ≥0.67 Criterion: Yes Point Estimate ≥1.0 Criterion: Yes

* Per-Protocol Immunogenicity Set included all subjects who had both baseline (or Study 2 Day 1 for Study 2) and post-vaccination immunogenicity samples, did not have SARS-CoV-2 infection at baseline (or Study 2 Day 1 for Study 2), did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest (Day 29 for Study 2 and Day 57 for Study 1).

[a] Number of subjects with non-missing data at the corresponding timepoint.

[b] Given the lack of randomization in Study 2, the statistical analysis plan pre-specified an analysis of covariance model for estimating the geometric mean titer that adjusts for differences in age groups (<65 years, ≥65 years).

[c] Immunobridging is declared if the lower limit of the 2-sided 95% CI for the GMR is >0.67 and the point estimate of the GLSM ratio is ≥1.0.

Note: Antibody values < the lower limit of quantitation (LLOQ) are replaced by 0.5 × LLOQ. Values > the upper limit of quantitation (ULOQ) are replaced by the ULOQ if actual values are not available.

GLSM = Geometric least squares mean

GMR = Geometric mean ratio

Table 8: Seroresponse Rates Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days Post-Booster Dose in Study 2 and 28 Days After Completion of the Primary Series in Study 1, Participants ≥18 Years of Age, Per-Protocol Immunogenicity Set*

Study 2 Booster Seroresponse[a] N[b]=149 n (%) (95% CI)[c]	Study 1 Primary Series Seroresponse[a] N[b]=1050 n (%) (95% CI)[c]	Difference in Seroresponse Rate (Study 2-Study 1) % (95% CI)[d]	Met Success Criterion[e]
131 (87.9) (81.6, 92.7)	1033 (98.4) (97.4, 99.1)	-10.5 (-16.7, -6.1)	Lower limit of 95% CI ≥-10% Criterion: No

* Per-Protocol Immunogenicity Set included all subjects who had both baseline (or Study 2 Day 1 for Study 2) and post-vaccination immunogenicity samples, did not have SARS-CoV-2 infection at baseline (or Study 2 Day 1 for Study 2), did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest (Day 29 for Study 2 and Day 57 for Study 1).

[a] Seroresponse is defined as ≥4-fold rise of pseudovirus neutralizing antibody titers (ID50) from baseline (pre-booster dose in Study 2 and pre-Dose 1 in Study 1), where baseline titers < LLOQ are set to LLOQ for the analysis.

[b] Number of subjects with non-missing data at both baseline and the post-baseline timepoint of interest.

[c] 95% CI is calculated using the Clopper-Pearson method.

[d] 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.

[e] Immunobridging is declared if the lower limit of the 2-sided 95% CI for the percentage difference is > -10%.

Study 2 participants who met the ≥4-fold increase in titer post-booster dose (87.9%) had a lower baseline GMT of 109 (range of individual titers 9, 4393), whereas Study 2 participants who did not meet the ≥4-fold increase in titers post-booster had a higher baseline GMT of 492 (range of individual titers 162, 2239).

An additional descriptive analysis evaluated seroresponse rates using baseline neutralizing antibody titers prior to Dose 1 of the primary series. As shown in Table 9 below, the booster dose seroresponse rate, with seroresponse defined as at least a 4-fold rise relative to the pre-Dose 1 titer, was 100%. The difference in seroresponse rates in this post-hoc analysis was 1.6% (95% CI -0.9, 2.6).

Table 9: Analysis of Seroresponse Rates Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days Post-Booster Dose in Study 2 and 28 Days After Completion of the Primary Series in Study 1, Participants ≥18 Years of Age, Per-Protocol Immunogenicity Set*

Study 2 Booster Seroresponse[a] N[b]=148 n (%) (95% CI)[d]	Study 1 Primary Series Seroresponse[a] N[c]=1050 n (%) (95% CI)[d]	Difference in Seroresponse Rate (After Booster-After Primary Series) % (95% CI)[e]
148 (100) (97.5, 100)	1033 (98.4) (97.4, 99.1)	1.6 (-0.9, 2.6)

* Per-Protocol Immunogenicity Set included all subjects who had non-missing data at baseline (before Dose 1) and 28 days post-booster in Study 2 or 28 days post-Dose 2 in the primary series in Study 1, respectively, did not have SARS-CoV-2 infection at pre-booster in Study 2 or baseline in Study 1, did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest.

[a] Seroresponse is defined as ≥4-fold rise of pseudovirus neutralizing antibody titers (ID50) from pre-Dose 1, where baseline titers < LLOQ are set to LLOQ for the analysis.

[b] Number of subjects with non-missing data at baseline (before Dose 1) and 28 days post-booster in Study 2.

[c] Number of subjects with non-missing data at baseline (before Dose 1) and 28 days post-Dose 2 in the primary series in Study 1.

[d] 95% CI is calculated using the Clopper-Pearson method.

[e] 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.

18.4 Immunogenicity of a Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine

Effectiveness of a Moderna COVID-19 Vaccine (0.25 mL) booster dose in individuals who completed primary vaccination with another authorized or approved COVID-19 Vaccine (heterologous booster dose) is inferred from immunogenicity data supporting effectiveness of a Moderna COVID-19 Vaccine (0.25 mL) booster dose administered following completion of a Moderna COVID-19 Vaccine primary series and from immunogenicity data from an independent Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose (0.5 mL) of the Moderna COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19

Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Moderna COVID-19 Vaccine (0.5 mL) was demonstrated regardless of primary vaccination.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection Multiple-Dose Vials are supplied as follows:

NDC 80777-273-99 Carton of 10 multiple-dose vials, each vial containing 5.5 mL

NDC 80777-273-98 Carton of 10 multiple-dose vials, each vial containing 7.5 mL

During storage, minimize exposure to room light.

Store frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2° to 8°C (36° to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (36° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (36° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (36° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (36° to 46°F) until use.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Dec/9/2021

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

NRS 239.320 Injury to, concealment or falsification of records or papers by public officer. An officer who mutilates, destroys, conceals, erases, obliterates or falsifies any record or paper appertaining to his or her office, is guilty of a category C felony and shall be punished as provided in NRS 193.130.

[Part 1911 C&P § 80; RL § 6345; NCL § 10029] — (NRS A 1979, 1463; 1995, 1264)

Falsifying and concealing pertinent data on Records and documents to Nevada Board of Health and therefore the public, medical boards and the Governor

"COVID 19 after vaccination" in Mr. Leguen's Southern Nevada Health District Report Dated December 3, 2021

On behalf of SNHD (one of the largest local public health organizations in the United States) Mr. Leguen reported and documented the number of positive cases amongst vaccinated and unvaccinated Nevada residents but did not disclose to the public the number of TESTS that were given to the vaccinated vs unvaccinated. Testing is taking place in a highly discriminatory manner with assumed disability by being unvaccinated. This is against the Americans with disability Act and American Civil Rights. Therefore, the unvaccinated are being subject to more aggressive testing schedules and requirements. Whereas vaccinated are required to test less frequently. In many cases vaccinated are not having to test to return to work or school after being sick with covid or exposed to covid but many unvaccinated are being required to test to go back to work or school or after being sick with covid or being exposed to covid or even to go to work at all on a weekly or more basis. Higher testing rates mathematically result in more positive cases per 10,000 residents as well as more positive cases overall. This is a fact, and these figures Mr. Leguen has documented to the NBOH and the public are not accurate and are being used to manipulate and falsify the data for covid cases in Nevada.

Mr. Leguen also conceals publicly available studies as well as facts from the CDC showing the percentages of recovery from covid. This doctor falsifies reporting by consistently stating "cases" and "deaths" without reporting to the public the extremely high recovery rate from covid nor the existing underlying conditions of the covid deaths resulting in a crime of covid misinformation.

These decisions to falsify and conceal information from the public, the Medical Boards, the hospitals, the Governor and many other important decision-making bodies has and is affecting Nevada residents' personal wellbeing on a grand scale by reinforcing discrimination in testing and treatment, promoting fear and promoting coercion via mandates and promoting potentially unfounded fear which is unknown due to the inaccurate covid misinformation being disseminated. The legal damages for these crimes may be limitless.

This information must be accurately documented and reported without concealing pertinent data as required by Nevada Law and is necessary for proper handling of the covid emergency. It is illegal to conceal, falsify or obliterate this information. The millions of Nevada residents affected by all of these decisions should be protected by the Nevada Law, the Nevada Constitution and The United States Constitution. Nevada residents should be protected by the oath in which Mr. Leguen took when he accepted this position as well as the oath he took as a medical doctor.