

You all continue to pass whatever you feel like passing. But, we are paying attention now. We know you want to compile a database of everyone's DNA and information at your will. If you make these changes, these will be career ending for you. The public will win legally, ethically and constitutionally and you will do jail time.

Yet you still have refused to disclose the dangers of the past Chief Medical officers LACK of disclosure of what he knows (attached PFIZER court ordered release of hundreds of pages of adverse events of the COVID vaccine he is still pushing causing death, nerve disorders, permanent heart damage, miscarriage, spontaneous abortion.....known since February 2021)

This is government overreach. We have a right to protect the medical information of our children if we so choose. We have a constitutional right to a religious exemption for a medical procedure or treatment that we do not want which you all somehow think you can just get around which is illegal. We have a right to deny a bodily invasive test we do not want. We have a right to deny any public information or DNA from being shared in any database or anywhere unless we approve and consent without coercion. Any law you make regarding this is invalid.

You should all go do something else or move to another country before you get found out with your disgusting acceptance of money over humans. Truth always prevails and it will be epic.

Do the right thing. Protect humans, protect privacy, protect freedom and for God sake you are the health board so actually try to help somebody!

*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**

<b>Acronym</b>	<b>Term</b>
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	175 <sup>a</sup>
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	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 ( $\geq 2\%$ ) 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**

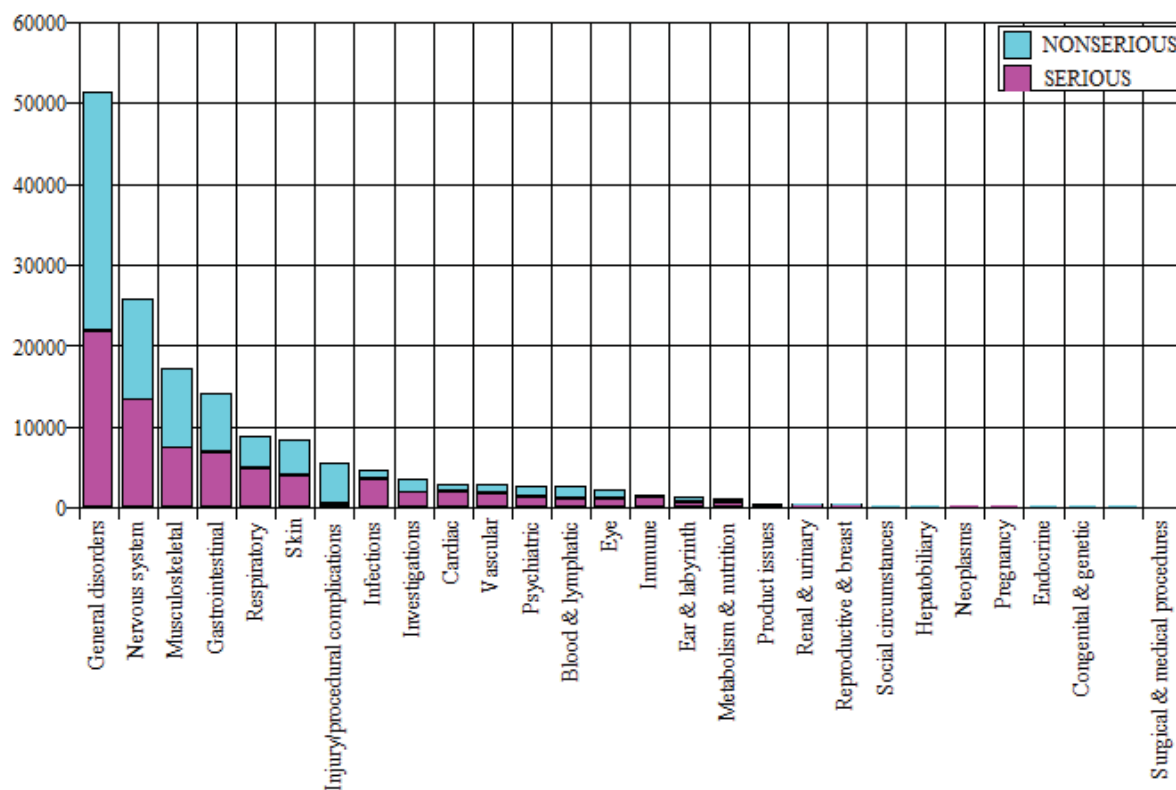


Table 2 shows the most commonly ( $\geq 2\%$ ) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

**Table 2. Events Reported in  $\geq 2\%$  Cases**

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

**Table 2. Events Reported in  $\geq 2\%$  Cases**

		<b>Cumulatively Through 28 February 2021</b>
<b>MedDRA SOC</b>	<b>MedDRA PT</b>	<b>AEs (AERP%) N = 42086</b>
	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%)
<b>Infections and infestations</b>		
	COVID-19	1927 (4.6%)
<b>Injury, poisoning and procedural complications</b>		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
<b>Musculoskeletal and connective tissue disorders</b>		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
<b>Nervous system disorders</b>		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Praesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
<b>Respiratory, thoracic and mediastinal disorders</b>		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
<b>Skin and subcutaneous tissue disorders</b>		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
<b>Total number of events</b>		<b>93473</b>

**3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan****Table 3. Safety concerns**

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

**Table 4. Important Identified Risk**

Topic	Description														
<b>Important Identified Risk</b>	<b>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)</b>														
Anaphylaxis	<p>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:</p> <table border="1"> <thead> <tr> <th>Brighton Collaboration Level</th><th>Number of cases</th></tr> </thead> <tbody> <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><i>Total</i></td><td>1833</td></tr> </tbody> </table> <p>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.</p> <p>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:</p> <p>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.</p> <p>Relevant event seriousness: Serious (2341), Non-Serious (617);</p> <p>Gender: Females (876), Males (106), Unknown (20);</p> <p>Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);</p> <p>Relevant even outcome<sup>a</sup>: fatal (9)<sup>b</sup>, resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);</p> <p>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).</p> <p>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.</p>	Brighton Collaboration Level	Number of cases	BC 1	290	BC 2	311	BC 3	10	BC 4	391	BC 5	831	<i>Total</i>	1833
Brighton Collaboration Level	Number of cases														
BC 1	290														
BC 2	311														
BC 3	10														
BC 4	391														
BC 5	831														
<i>Total</i>	1833														

<sup>a</sup> Different clinical outcome may be reported for an event that occurred more than once to the same individual.

<sup>b</sup> 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)	<p>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.</p> <p>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<sup>a</sup>.</p> <p>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:</p> <p>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).</p> <p>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.</p> <p>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.</p>

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	<ul style="list-style-type: none"> <li>Number of cases: 413<sup>a</sup> (0.98% of the total PM dataset); 84 serious and 329 non-serious;</li> <li>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.</li> </ul> <p>Pregnancy cases: 274 cases including:</p> <ul style="list-style-type: none"> <li>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).</li> <li>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).</li> <li>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).</li> <li>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).</li> <li>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.</li> </ul> <p>Breast feeding baby cases: 133, of which:</p> <ul style="list-style-type: none"> <li>116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events;</li> <li>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).</li> </ul> <p>Breast feeding mother cases (6):</p> <ul style="list-style-type: none"> <li>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</li> <li>1 non-serious case reported with very limited information and without associated AEs.</li> </ul>

**Table 6. Description of Missing Information**

Topic	Description
<b>Missing Information</b>	<p><b>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)</b>  <b>Total Number of Cases in the Reporting Period (N=42086)</b></p> <ul style="list-style-type: none"> <li>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).</li> </ul> <p>Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.</p>
Use in Paediatric Individuals <12 Years of Age	<p><u>Paediatric individuals &lt;12 years of age</u></p> <ul style="list-style-type: none"> <li>Number of cases: 34<sup>d</sup> (0.1% of the total PM dataset), indicative of administration in paediatric subjects &lt;12 years of age;</li> <li>Country of incidence: UK (29), US (3), Germany and Andorra (1 each);</li> <li>Cases Seriousness: Serious (24), Non-Serious (10);</li> <li>Gender: Females (25), Males (7), Unknown (2);</li> <li>Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0;</li> <li>Case outcome: resolved/resolving (16), not resolved (13), and unknown (5).</li> <li>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).</li> </ul> <p>Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.</p>
Vaccine Effectiveness	<p>Company conventions for coding cases indicative of lack of efficacy:</p> <p>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:</p> <ul style="list-style-type: none"> <li>PT “Vaccination failure” is coded when ALL of the following criteria are met: <ul style="list-style-type: none"> <li>The subject has received the series of two doses per the dosing regimen in local labeling.</li> <li>At least 7 days have elapsed since the second dose of vaccine has been administered.</li> <li>The subject experiences SARS-CoV-2 infection (confirmed laboratory tests).</li> </ul> </li> <li>PT “Drug ineffective” is coded when either of the following applies: <ul style="list-style-type: none"> <li>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”.</li> <li>It is unknown: <ul style="list-style-type: none"> <li>Whether the subject has received the series of two doses per the dosing regimen in local labeling;</li> <li>How many days have passed since the first dose (including unspecified number of days like “a few days”, “some days”, etc.);</li> <li>If 7 days have passed since the second dose;</li> </ul> </li> <li>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.</li> </ul> </li> </ul> <p>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.</p> <p>Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:</p>

**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"
	<p><b>Lack of efficacy cases</b></p> <ul style="list-style-type: none"> <li>Number of cases: 1665<sup>b</sup> (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;</li> <li>Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)<sup>f</sup>].</li> <li>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.</li> <li>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).</li> <li>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.</li> </ul> <p><b>Drug ineffective cases (1649)</b></p> <ul style="list-style-type: none"> <li>Drug ineffective event seriousness: serious (1625), non-serious (21)<sup>e</sup>;</li> <li>Lack of efficacy term was reported: <ul style="list-style-type: none"> <li>after the 1st dose in 788 cases</li> <li>after the 2nd dose in 139 cases</li> <li>in 722 cases it was unknown after which dose the lack of efficacy occurred.</li> </ul> </li> <li>Latency of lack of efficacy term reported after the first dose was known for 176 cases: <ul style="list-style-type: none"> <li>Within 9 days: 2 subjects;</li> <li>Within 14 and 21 days: 154 subjects;</li> <li>Within 22 and 50 days: 20 subjects;</li> </ul> </li> <li>Latency of lack of efficacy term reported after the second dose was known for 69 cases: <ul style="list-style-type: none"> <li>Within 0 and 7 days: 42 subjects;</li> <li>Within 8 and 21 days: 22 subjects;</li> <li>Within 23 and 36 days: 5 subjects.</li> </ul> </li> <li>Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases: <ul style="list-style-type: none"> <li>Within 0 and 7 days after vaccination: 281 subjects.</li> <li>Within 8 and 14 days after vaccination: 89 subjects.</li> <li>Within 15 and 44 days after vaccination: 39 subjects.</li> </ul> </li> </ul> <p>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</p>		

**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)
	<p>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.</p> <p><b><i>Vaccination failure cases (16)</i></b></p> <ul style="list-style-type: none"> <li>• Vaccination failure seriousness: all serious;</li> <li>• Lack of efficacy term was reported in all cases after the 2nd dose;</li> <li>• Latency of lack of efficacy was known for 14 cases: <ul style="list-style-type: none"> <li>○ Within 7 and 13 days: 8 subjects;</li> <li>○ Within 15 and 29 days: 6 subjects.</li> </ul> </li> </ul> <p>COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases.</p> <p>Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.</p>

- 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.
- 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.
- 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
- 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.
- Different clinical outcomes may be reported for an event that occurred more than once to the same individual
- 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, HLGs 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**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
<b>Anaphylactic Reactions</b> <i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria</i>	Please refer to the Risk 'Anaphylaxis' included above in <a href="#">Table 4</a> .
<b>Cardiovascular AESIs</b> <i>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</i>	<ul style="list-style-type: none"> <li>• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed;</li> <li>• 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;</li> <li>• Subjects' gender: female (1076), male (291) and unknown (36);</li> <li>• Subjects' age group (n = 1346): Adult<sup>c</sup> (1078), Elderly<sup>d</sup> (266) Child<sup>e</sup> and Adolescent<sup>f</sup> (1 each);</li> <li>• Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events;</li> <li>• 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);</li> <li>• Relevant event onset latency (n = 1209): Range from &lt;24 hours to 21 days, median &lt;24 hours;</li> </ul>



**Table 7. AESIs Evaluation for BNT162b2**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
	<ul style="list-style-type: none"> <li>Relevant event outcome<sup>g</sup>: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380);</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<b>COVID-19 AESIs</b> <i>Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia</i>	<ul style="list-style-type: none"> <li>Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed;</li> <li>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;</li> <li>Subjects' gender: female (1650), male (844) and unknown (573);</li> <li>Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant<sup>h</sup> and Adolescent (2 each), Child (1);</li> <li>Number of relevant events: 3359, of which 2585 serious, 774 non-serious;</li> <li>Most frequently reported relevant PTs (&gt;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);</li> <li>Relevant event onset latency (n = 2070): Range from &lt;24 hours to 374 days, median 5 days;</li> <li>Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<b>Dermatological AESIs</b> <i>Search criteria: PT Chillblains; Erythema multiforme</i>	<ul style="list-style-type: none"> <li>Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed;</li> <li>Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries;</li> <li>Subjects' gender: female (17) male and unknown (1 each);</li> <li>Subjects' age group (n=19): Adult (18), Elderly (1);</li> <li>Number of relevant events: 20 events, 16 serious, 4 non-serious</li> </ul>

**Table 7. AESIs Evaluation for BNT162b2**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
	<ul style="list-style-type: none"> <li>Reported relevant PTs: Erythema multiforme (13) and Chillblains (7)</li> <li>Relevant event onset latency (n = 18): Range from &lt;24 hours to 17 days, median 3 days;</li> <li>Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<b>Haematological AESIs</b> <i>Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms)</i>	<ul style="list-style-type: none"> <li>Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed;</li> <li>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;</li> <li>Subjects' gender (n=898): female (676) and male (222);</li> <li>Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1);</li> <li>Number of relevant events: 1080, of which 681 serious, 399 non-serious;</li> <li>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 hematoma (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);</li> <li>Relevant event onset latency (n = 787): Range from &lt;24 hours to 33 days, median = 1 day;</li> <li>Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<b>Hepatic AESIs</b> <i>Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury</i>	<ul style="list-style-type: none"> <li>Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed;</li> <li>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;</li> <li>Subjects' gender: female (43), male (26) and unknown (1);</li> <li>Subjects' age group (n=64): Adult (37), Elderly (27);</li> </ul>



**Table 7. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
	<ul style="list-style-type: none"> <li>Number of relevant events: 94, of which 53 serious, 41 non-serious;</li> <li>Most frequently reported relevant PTs (<math>\geq 3</math> 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);</li> <li>Relevant event onset latency (n = 57): Range from &lt;24 hours to 20 days, median 3 days;</li> <li>Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<b>Facial Paralysis</b> <i>Search criteria: PTs Facial paralysis, Facial paresis</i>	<ul style="list-style-type: none"> <li>Number of cases: 449<sup>i</sup> (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed;</li> <li>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;</li> <li>Subjects' gender: female (295), male (133), unknown (21);</li> <li>Subjects' age group (n=411): Adult (313), Elderly (96), Infant<sup>j</sup> and Child (1 each);</li> <li>Number of relevant events<sup>k</sup>: 453, of which 399 serious, 54 non-serious;</li> <li>Reported relevant PTs: Facial paralysis (401), Facial paresis (64);</li> <li>Relevant event onset latency (n = 404): Range from &lt;24 hours to 46 days, median 2 days;</li> <li>Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97);</li> </ul> <p>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</p>

**Table 7. AESIs Evaluation for BNT162b2**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
<b>Immune-Mediated/Autoimmune AESIs</b> <i>Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity</i>	<p>2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.</p> <ul style="list-style-type: none"> <li>• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed;</li> <li>• Country of incidence (&gt;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.</li> <li>• Subjects' gender (n=682): female (526), male (156).</li> <li>• Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2).</li> <li>• Number of relevant events: 1077, of which 780 serious, 297 non-serious.</li> <li>• Most frequently reported relevant PTs (&gt;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);</li> <li>• Relevant event onset latency (n = 807): Range from &lt;24 hours to 30 days, median &lt;24 hours.</li> <li>• Relevant event outcome<sup>1</sup>: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<b>Musculoskeletal AESIs</b> <i>Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial<sup>1</sup>; Chronic fatigue syndrome; Polyarthrititis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis</i>	<ul style="list-style-type: none"> <li>• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed;</li> <li>• 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;</li> <li>• Subjects' gender (n=3471): female (2760), male (711);</li> <li>• Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1);</li> <li>• Number of relevant events: 3640, of which 1614 serious, 2026 non-serious;</li> <li>• Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthrititis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1);</li> <li>• Relevant event onset latency (n = 2968): Range from &lt;24 hours to 32 days, median 1 day;</li> </ul>

**Table 7. AESIs Evaluation for BNT162b2**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
	<ul style="list-style-type: none"> <li>Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<b>Neurological AESIs (including demyelination)</b> <i>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</i>	<ul style="list-style-type: none"> <li>Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed.</li> <li>Country of incidence (<math>\geq 9</math> 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.</li> <li>Subjects' gender (n=478): female (328), male (150).</li> <li>Subjects' age group (n=478): Adult (329), Elderly (149);</li> <li>Number of relevant events: 542, of which 515 serious, 27 non-serious.</li> <li>Most frequently reported relevant PTs (<math>&gt;2</math> 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);</li> <li>Relevant event onset latency (n = 423): Range from <math>&lt;24</math> hours to 48 days, median 1 day;</li> <li>Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161);</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<b>Other AESIs</b> <i>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</i>	<ul style="list-style-type: none"> <li>Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed;</li> <li>Country of incidence (<math>&gt; 20</math> 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;</li> <li>Subjects' gender (n=7829): female (5969), male (1860);</li> <li>Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);</li> </ul>

**Table 7. AESIs Evaluation for BNT162b2**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
<i>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</i>	<ul style="list-style-type: none"> <li>• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious;</li> <li>• Most frequently reported relevant PTs (<math>\geq 6</math> 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);</li> <li>• Relevant event onset latency (n =6836): Range from &lt;24 hours to 61 days, median 1 day;</li> <li>• Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<b>Pregnancy Related AESIs</b> <i>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</i>	<p>For relevant cases, please refer to <a href="#">Table 6</a>, Description of Missing Information, Use in Pregnancy and While Breast Feeding</p>
<b>Renal AESIs</b> <i>Search criteria: PTs Acute kidney injury; Renal failure.</i>	<ul style="list-style-type: none"> <li>• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed;</li> <li>• 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);</li> <li>• Subjects' gender: female (46), male (23);</li> <li>• Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1);</li> <li>• Number of relevant events: 70, all serious;</li> <li>• Reported relevant PTs: Acute kidney injury (40) and Renal failure (30);</li> <li>• Relevant event onset latency (n = 42): Range from &lt;24 hours to 15 days, median 4 days;</li> <li>• Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<b>Respiratory AESIs</b> <i>Search criteria: Lower respiratory tract infections NEC (HLT)</i>	<ul style="list-style-type: none"> <li>• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;</li> </ul>

**Table 7. AESIs Evaluation for BNT162b2**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
<p><i>(Primary Path) OR Respiratory failures (excl neonatal) (HLT)</i>  <i>(Primary Path) OR Viral lower respiratory tract infections (HLT)</i>  <i>(Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome</i></p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Subjects' gender (n=130): female (72), male (58).</li> <li>• Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1).</li> <li>• Number of relevant events: 137, of which 126 serious, 11 non-serious;</li> <li>• 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).</li> <li>• Relevant event onset latency (n=102): range from &lt; 24 hours to 18 days, median 1 day;</li> <li>• Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<p><b>Thromboembolic Events</b>  <i>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</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed;</li> <li>• 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;</li> <li>• Subjects' gender (n= 144): female (89), male (55);</li> <li>• Subjects' age group (n=136): Adult (66), Elderly (70);</li> <li>• Number of relevant events: 168, of which 165 serious, 3 non-serious;</li> <li>• Most frequently reported relevant PTs (&gt;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);</li> <li>• Relevant event onset latency (n = 124): Range from &lt;24 hours to 28 days, median 4 days;</li> <li>• Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<p><b>Stroke</b>  <i>Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed;</li> <li>• Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),</li> </ul>



**Table 7. AESIs Evaluation for BNT162b2**

<b>AESIs<sup>a</sup></b> <b>Category</b>	<b>Post-Marketing Cases Evaluation<sup>b</sup></b> <b>Total Number of Cases (N=42086)</b>
<i>(Primary Path) OR HLT</i> <i>Cerebrovascular venous and sinus thrombosis (Primary Path)</i>	<p>Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries;</p> <ul style="list-style-type: none"> <li>Subjects' gender (n= 273): female (182), male (91);</li> <li>Subjects' age group (n=265): Adult (59), Elderly (205), Child<sup>m</sup> (1);</li> <li>Number of relevant events: 300, all serious;</li> <li>Most frequently reported relevant PTs (&gt;1 occurrence) included: <ul style="list-style-type: none"> <li>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);</li> <li>PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranial and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each);</li> </ul> </li> <li>Relevant event onset latency (n = 241): Range from &lt;24 hours to 41 days, median 2 days;</li> <li>Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<b>Vasculitic Events</b> <i>Search criteria: Vasculitides HLT</i>	<ul style="list-style-type: none"> <li>Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed;</li> <li>Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa Rica (1 each);</li> <li>Subjects' gender: female (26), male (6);</li> <li>Subjects' age group (n=31): Adult (15), Elderly (16);</li> <li>Number of relevant events: 34, of which 25 serious, 9 non-serious;</li> <li>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);</li> <li>Relevant event onset latency (n = 25): Range from &lt;24 hours to 19 days, median 3 days;</li> <li>Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8).</li> </ul> <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>

**Table 7. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
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- 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<sup>1</sup> that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056<sup>2</sup> (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)<sup>3</sup>,
- Recovered/recovering (354, of which 4 are serious),
- Recovered with sequelae (8, of which 3 serious)

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<sup>1</sup> 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.

<sup>2</sup> Thirty-five (35) cases were excluded 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.

<sup>3</sup> 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 ( $\geq 12$  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)**

ME PTs	Serious		Non-Serious	
	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)**

ME PTs	Serious		Non-Serious	
	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;Lamb'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; Polyarthritides; 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.



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Health Resources &amp; Services Administration



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# 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. Claims filed alleging injuries and deaths from COVID-19 countermeasures](#)
- [Table 2. Compensated claims](#)
- [Table 3. Eligible for compensation but no reported eligible expenses](#)
- [Table 4. Denied because required medical records were not submitted](#)
- [Table 5. Denied for failure to meet the standard of proof and/or sustain a covered injury](#)
- [Table 6. Ineligible for missing the filing deadline](#)
- [Table 7. Ineligible because product is not covered by CICP](#)
- [Table 8. Ineligible due to no allegation of administration or use of a covered countermeasure](#)

**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 / Rhabdomyolysis / 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 Venous 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 Cardiomyopathy	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	Leukocyto 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	Phantomia	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 Recurrence	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 Venous 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 / Ondansetron	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
Peramivir / 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
<b>Total COVID-19</b>		<b>3,158</b>

**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-Barré 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
<b>Total</b>			<b>\$6,076,087.47</b>

**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	Paresthesias
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 ↕
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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 Haemophilus 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



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NEVADA STATE BOARD OF HEALTH  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way, Suite 300  
CARSON CITY, NV 89706

**APPLICATION FOR VARIANCE**

Please check the appropriate box that pertains to the NAC for which you are requesting a variance.



Division Administration

(NAC 439, 441A, 452, 453A, & 629)



Health Care Quality & Compliance

(NAC 449, 457, 459 & 652)



Child, Family & Community Wellness

(NAC 392, 394, 432A, 439, 441A, & 442)



Health Statistics, Planning,

Epidemiology and Response

(NAC 440, 450B, 452, 453, 453A, & 695C)



Public Health & Clinical Services

(NAC 211, 444, 446, 447, 583, & 585)

Date: 10/22/2021

Name of Applicant: Cameron Mathew Rose

Phone: 775-683-7487

Mailing Address: Exel Keystone Ave Box #257

City: Reno

State: NV

Zip: 89503

We do hereby apply for a variance to

chapter/section

Administrative Code (NAC). (For example: NAC 449.204)

of the Nevada

NAC 439 and 441A

Title of section in  
question:

Covid-19 mandated vaccine for enrollment at Universities in Nevada

Statement of existing or proposed conditions in violation of the NAC:

The Covid-19 mandate would subject me to an exceptional and undue hardship of returning back to being homeless as I am against unnecessary use of pharmaceuticals as a treatment. Where the mandate does not follow the least restrictive manner and takes away my treatment options without a court order for an involuntary treatment of which is unnecessary and is not for the benefit of the health of myself or others as I have a healthy immune system that does not get sick.



NEVADA STATE BOARD OF HEALTH  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way, Suite 300  
CARSON CITY, NV 89706

**APPLICATION FOR VARIANCE**

Date of initial operation (if existing): For winter and spring 2022 semesters

**ATTENTION:** Please read this section closely. Your request for variance will be examined against these criteria:

Any person who, because of unique circumstances, is unduly burdened by a regulation of the State Board of Health and thereby suffers a hardship and the abridgement of a substantial property right may apply for a variance from a regulation. (NAC 439.200(1))

1. The State Board of Health will grant a variance from a regulation only if it finds from the evidence presented at the hearing that:

(a) There are circumstances or conditions which:

- (1) Are unique to the applicant;
- (2) Do not generally affect other persons subject to the regulation;
- (3) Make compliance with the regulation unduly burdensome; and
- (4) Cause a hardship to and abridge a substantial property right of the applicant; and

(b) Granting the variance:

- (1) Is necessary to render substantial justice to the applicant and enable him to preserve and enjoy his property; and
- (2) Will not be detrimental or pose a danger to public health and safety.

2. Whenever an applicant for a variance alleges that he suffers or will suffer economic hardship by complying with the regulation, he must submit evidence demonstrating the costs of his compliance with the regulation. The Board will consider the evidence and determine whether those costs are unreasonable. (NAC 439.240)

Therefore, it is important for your variance request to be as complete as possible. It is your responsibility to attach documentation supportive of your variance request.

Statement of degree of risk of health

I avoid pharmaceuticals unless there is no other treatment options available. For example, infections are remedied with antibiotics with limited to no side effects. Other treatment options exist without the vaccine of which the vaccine does not provide protection from infection. And this is a component as to why I have great health is my avoidance of pharmaceuticals and unnecessary treatments. Where I feel the vaccine will compromise my immunity where my immune system is working as it should with out it.



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APPLICATION FOR VARIANCE

Please state in detail the circumstances or conditions which demonstrate that:

1. An exceptional and undue hardship results from a strict application of the Regulation:

Would result in my return to being homeless. I am against the treatment as I am against all pharmaceuticals unless no other alternatives exist because I was forced medicated as a child where I feel the vaccine would violate an over 20 year (Aug 26<sup>th</sup> 2001) avoidance of pharmaceuticals through the unnecessary treatment.

2. The variance, if granted, would not:

- A. Cause substantial detriment to the public welfare.

By returning back to being homeless, would actually cause more of a detriment to public welfare over staying in school because I would be less likely to infect others under quarantine over being forced to live in public view at all times, if I happened to become infected by Covid-19. Where instruction would only be less for the duration of the sickness and not a full semester or longer.

- B. Impair substantially the purpose of the regulation from which the application seeks a variance.

The purpose of the regulation is so that we can return back to normal instruction. Yet, we have returned to a more traditional form of normal instruction without a mandated vaccine. Where the Covid-19 vaccine does not prevent infection. And where without the vaccine I still have not been sick even once since my year and a half with the university of Nevada, Reno.

The bureau may require the following supporting documents to be submitted with and as a part of this application:

1. Legal description of property concerned

2. General area identification map



NEVADA STATE BOARD OF HEALTH  
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**APPLICATION FOR VARIANCE**

- \_ 3. Plat map showing locations of all pertinent items and appurtenances
- \_ 4. Well log (if applicable)
- \_ 5. Applicable lab reports
- \_ 6. Applicable engineering or construction/remodeling information
- \_ 7. Other items (see following pages)

This application must be accompanied by evidence demonstrating the costs of your compliance with regulations or specific statutory standards. Your request will be placed on the Board of Health agenda 40 days or more after receipt in this office if accompanied by the required fee (NAC 439.210). The application and supporting documentation will form the basis for the Division of Public and Behavioral Health staff report and recommendation(s) to the Board. Failure to respond to the above statements may cause the Board to deny consideration of the application at the requested Board meeting.

Please schedule this hearing during:



The next regularly scheduled Board of Health meeting, regardless of location.



The next scheduled meeting in Carson City.



The next scheduled meeting in Las Vegas.

Signature:

CMSMR

Printed Name:

Cameron Matthew Rose

Title:

Date:

10/22/2021

## Declaration of Economic Hardship.

I, Cameron Mathew Rose, who is applying for a variance through the State Board of Health, do declare that I suffer from economic hardship and request that the fees associated for submitting and filing the application for variance be waived.

I am a student with only a Social Security Disability Income and no other source of income. Of which I would not be able to pay the fees in order to have my application for a variance to be heard.

Therefore, I respectfully request to have the fees waived and my application for variance pushed forward to continue the process.

10/22/2021

C.M.J.M.R.

Signature

Cameron Mathew Rose



# Action Item #4 - Variance Case #728 Cameron Rose

Wednesday, December 1, 2021 3:21 PM

It sounds like Cameron may have had a former addiction and that he may be reliant on student housing for shelter. He is also on disability income. Did anyone bother to ask him about that while you were playing God with his life?

By the way have you read the recent court ordered Pfizer trial release November 23rd? I attached a copy of the excerpt for you on my email submission. Did you know that they had 93,473 adverse events reported, 1,223 fatalities and 1,927 individuals got COVID from the vaccine trials ... and Pfizer knew all of this in February of 2021. And that was just Pfizer's trial. We have not seen Moderna or J & J. If I were you, I would not want that blood on my hands.

So Mr. Azzam stated that COVID has "Killed 7,850 NV residents" - According to CDC Deaths under the age 45 attribute to **4.1% of the nationwide deaths**. That's 322 deaths under 45 in Nevada through the pandemic period. Since the CDC always makes it so difficult to get actual numbers by age ranges I had to divide that by average death per age year which equals 7.1555. Multiply now 7.1555 for a 14 year range of average college 17-30. So 14 years x 7.1555 equals 101 deaths in the approximate college age range. (If these numbers are even correct due to the bonus payments from CMS for positive COVID case reporting) And we have no idea if any of these had diabetes, cancer, hypertension or any other underlying condition. We also don't even know how many were even college students.

So the fact that Nevada even passed this sweeping mandate unanimously for over 108,000 college students in the entire state with these numbers tells me **NOT ONE** of you are doing your own research or you just don't care because there is some alternate benefit or agenda for you personally because it is blatantly non sensical as you would save more lives removing bad food and mandating exercise.

Mr. Azzam - "Vaccine is very effective and "safe" in reducing and preventing severe infections, hospitalizations and death" **NO IT IS DOES NOT PREVENT SEVERE INFECTION OR HOSPITALIZATION OR DEATH. THE REPORT FROM SNHD JUST SAID THERE WERE MULTIPLE DEATHS IN THE VACCINATED. SO, NOT EFFECTIVE OR SAFE FOR EVERYONE AND DO YOU KNOW WHO WILL HAVE AN ADVERSE EFFECT WHEN YOU ARE BLANKETING THESE MANDATES?**

CDC and D.r Fauci have told us now that the vaccine does not stop the spread or the contraction of the virus.

Men in particular are at risk of myocarditis and pericarditis per FDA. There are athletes that are collapsing from heart issues and getting blood clots.

**This vaccine could cause exceptional undue hardship for Cameron by giving him myocarditis, maiming him with Gullian Barre or any of the other 30,000 other adverse issues reported on VAERS. Hundreds of other pharmaceuticals have been pulled from the market for less than 100 deaths. So really the question is, why do you all want this shot in people so badly?**

Cameron should not be asking for a Variance, he should be suing you in the mass lawsuit that is currently being compiled. (By the way Contact Joey Gilbert in Reno Cameron) You should also be recognizing natural immunity.

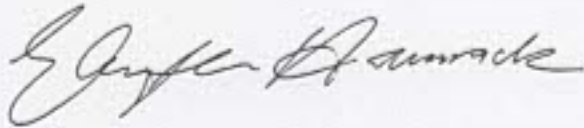
I have emailed studies on that as well from Harvard etc. Cameron would also have a greater chance of becoming a detriment to society should you force him out of school. He is better off for the overall well being of our society to finish school..

NAC 441A 755 should be eradicated it is ridiculous anyway as it states "proof of immunity" required, no



one in the world can provide that first of all and we all know this vaccine does not make anyone IMMUNE. Your mandate is a violation of the constitution and higher courts are currently making these rulings as we speak. Attorneys in Nevada are chomping at the bit. You will all get paid regardless, but the public will soon know you all participated in this against Nuremberg Code due to this being a trial and experimental which it says right on Pfizer, Moderna and J&J web sites that these shots are NOT FDA approved.

My suggestion is to Give ALL students that do not want this vaccine a Variance if that's all you got and God Bless this young man for trying to go to school on disability income and with no place to live where is your soul?

A handwritten signature in black ink, appearing to read "Elizabeth Hammack". The signature is fluid and cursive, with the first name "Elizabeth" and last name "Hammack" clearly distinguishable.

Elizabeth Hammack - Henderson, NV



Steve Sisolak  
Governor

Richard Whitley, MS  
Director



**DEPARTMENT OF  
HEALTH AND HUMAN SERVICES**  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
*Helping people. It's who we are and what we do.*



Lisa Sherych  
Administrator

Ihsan Azzam,  
Ph.D., M.D.  
Chief Medical Officer

## MEMORANDUM

**DATE:** November 16, 2021

**TO:** Jon Pennell, DVM, Chairperson, State Board of Health

**FROM:** Ihsan Azzam, Ph.D., M.D., Chief Medical Officer, State of Nevada

**RE:** Variance Case #728 – Cameron Rose - variance to Nevada Administrative Code (NAC) 439 and 441a.

### Staff Review

The Secretary of the Board of Health, at the Division of Public and Behavioral Health, received an Application for Variance ("Application") from Cameron Rose ("Applicant"), requesting the Nevada State Board of Health to grant a variance waiving the requirements of NAC 441A.775, as amended by the Emergency Regulation adopted August 20, 2021, requiring any individual enrolling in a Nevada university, community college, or state college, on or after November 1, 2021, to provide proof of a completed COVID-19 vaccination series.

### INTENT OF THE REGULATION

The Nevada State Board of Health unanimously approved COVID-19 vaccine requirements for Nevada System of Higher Education (NSHE) students at an emergency meeting held Friday, August 20, 2021. This regulation requires all students in NSHE institutions to be fully vaccinated for COVID-19 and to provide proof of vaccination to be able to enroll when Spring 2022 semester enrollment opens on November 1st, 2021.

Since March 2021, COVID-19 infected more than 450,000 and killed 7,850 Nevada residents. The pandemic is ongoing and COVID-19 continues to spread, replicate and actively mutate. COVID-19 vaccine is very effective and safe in reducing and preventing severe COVID-19 infections, hospitalizations and death.

The Centers for Disease Control and Prevention (CDC) recommends all eligible individuals receive a COVID-19 vaccine as soon as possible, as fully vaccinated individuals can start resuming pre-pandemic activities. Similarly, on August 5, 2021, the Governor Sisolak's Medical Advisory Team recommended that Nevada should require all post-secondary students within NSHE institutions to become fully vaccinations for COVID-19. The only way to control this pandemic is through vaccinating all eligible individuals in Nevada as soon as possible.



## EXCEPTIONAL AND UNDUE HARDSHIP

The Applicant asserts that he is against all pharmaceuticals unless no other alternatives exist, stating that he is on Social Security Disability and compliance with the mandate will result in him becoming homeless. However, it is unclear from his application how the requirements of NAC 441A.755 will result in the applicant "being homeless." To the extent that the Applicant has a religious or medical basis for refusing the vaccine, such an accommodation may be sought through the NSHE institution he attends. However, with no other indication as to how the regulations causes a unique hardship to the Applicant, the statements within the Application suggest that the Applicant has a philosophical objection with the COVID-19 vaccine, and pharmaceuticals more broadly. Such objections do not create an exceptional or undue hardship which would justify a variance.

As recently emerging COVID-19 lineages such as the delta variant are highly transmissible, and as infective as the varicella virus, unvaccinated individuals can certainly cause an increased risk to other students and staff in the university houses, dorms and other NSHE facilities.

Similarly of note, vaccinating the homeless population in Nevada is high priority. Homeless individuals pose a very high risk for contracting and transmitting COVID-19 to other individuals in homeless shelters. Additionally, due to very high rates of mortality due to COVID-19 among the homeless in Nevada, vaccinating the homeless population was one of the highest priorities for the State Division of Public and Behavioral Health (DPBH).

It has been determined by the Governor's Medical Advisory Team and the Nevada Board of Health that the COVID-19 vaccine is necessary for the safety of NSHE students and staff.

## DEGREE OF RISK TO HEALTH AND SAFETY

The Applicant has asserted that the variance, if granted, would not cause substantial detriment to public welfare, as he would be less likely to infect others while enrolled in school than if he were homeless. As noted above, the risk of transmission is high in both homeless communities and educational institutions. The Governor's Medical Advisory Team has recommended that to ensure student safety, all post-secondary students within NSHE institutions should be required to receive the COVID-19 vaccine. The failure of eligible individuals to receive the COVID-19 vaccine causes an increased risk of transmission to other students in NSHE facilities.

The Applicant further asserts that the variance, if granted, would not impair substantially the purpose of the regulation. However, as stated above, the intent of this regulation to protect all students and staff at NSHE institutions per the recommendations of the CDC and the Governor's Medical Advisory Team.

According to the CDC, Food and Drug Administration (FDA) and numerous national and international studies and research, the COVID-19 vaccine is safe and effective.<sup>1</sup> Under the most intense safety monitoring in the United States (U.S.) history, more than 432 million doses of COVID-19 vaccine have been given in the U.S. from December 14, 2020, through November 8, 2021.

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<sup>1</sup><https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=%E2%80%A2%20COVID%2D19%20vaccines,as%20soon%20as%20possible>.



## CRITERIA FOR DENYING VARIANCE

Pursuant to NRS 439.200(3), the Board of Health may grant a variance waiving the requirements of a regulation, if it finds that:

- (a) Strict application of that regulation would result in exceptional and undue hardship to the person requesting the variance; and
- (b) The variance, if granted, would not:
  - (1) Cause substantial detriment to the public welfare; or
  - (2) Impair substantially the purpose of that regulation.

The Applicant, in asserting a philosophical objection to the COVID-19 mandate, has not established the exception and undue hardship, unique to this individual. Philosophical objections to the COVID-19 vaccine, or more broadly, pharmaceuticals, do not constitute a unique circumstance which would justify the granting of a variance. The regulation, which allows for accommodations due to religious or medical reasons, does not provide a philosophical exemption, as sought here.

Further, for the reasons stated above, if granted, this variance would cause substantial detriment to the public welfare and substantially impair the purpose of NAC 441A.755.

Denying this variance request is consistent with CDC recommendations and would be in the best interest of the Applicant, other students, and staff in the NSHE and the Nevada community as a whole. Receiving the COVID-19 vaccine is the only way to protect him and others from contracting severe COVID-19 infection and transmitting it to other individuals or even dying from it.

## PUBLIC COMMENT RECEIVED

None.

## STAFF RECOMMENDATION

Staff recommends the State Board of Health deny the variance for Case #728.

PRESENTER: Ihsan Azzam, Ph.D., M.D., Chief Medical Officer, State of Nevada



Steve Sisolak  
Governor

Richard Whitley, MS  
Director



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Lisa Sherych  
Administrator

Ihsan Azzam,  
Ph.D., M.D.  
Chief Medical Officer

## NOTICE OF PUBLIC HEARING

### CAMERON MATHEW ROSE IS REQUESTING A VARIANCE, #728, FROM THE NEVADA STATE BOARD OF HEALTH REGULATIONS.

NOTICE IS HEREBY GIVEN that CAMERON MATHEW ROSE has requested a variance from Nevada Administrative Code (NAC) 441A.755, as amended by the Emergency Regulation of the Board of Health, effective August 20, 2021.

A public hearing will be conducted on December 3<sup>rd</sup>, 2021, at 9:00 am by the Nevada State Board of Health to consider this request. This meeting will be held online.

#### Meeting Locations:

#### Join from computer using the Zoom meeting link:

<https://zoom.us/j/91711965467?pwd=WDc0MWJUVnZGRRC85VEp1QnNUUExIZz09>

Online Conference ID Number: 917 1196 5467

Passcode: 422977

#### Join by Phone:

1-669-900-9128 (San Jose) Access Code: 917 1196 5467

Passcode: 422977

Phone Conference ID Number: 439 309 712#

The CAMERON MATHEW ROSE is requesting a variance from NAC 441A.755, as amended by the Emergency Regulation of the Board of Health which states:

**NAC 441A.755 University, Community college, and State college students: Proof of immunity to certain communicable diseases required; exceptions; exclusion from university, community college, state college. (NRS 441A.120)**

1. Except as otherwise provided in subsection ~~10~~ 11 or unless excused because of religious belief or medical condition, a person shall not attend a university until he submits to the university proof of immunity to tetanus, diphtheria, measles, mumps, rubella, and any other disease specified by the State Board of Health. The Division shall establish the immunization schedule required for admission of the student.



*2. Except as otherwise provided in subsection 11 or unless excused because of religious belief or medical condition, a person shall not enroll in courses at a university, community college, or state college on or after November 1, 2021, unless the person submits to the institution proof of a completed COVID-19 vaccination series.*

~~{2.}~~3. Except as otherwise provided in subsection ~~{10}~~ 11 or unless excused because of religious belief or medical condition, a person who:

(a) Is less than 23 years of age; and

(b) Is enrolled as a freshman;

Ê shall not attend a university until he or she submits to the university proof of immunity to Neisseria meningitidis. The Division shall establish the immunization schedule required for admission of the student.

~~{3.}~~4. *Except as required by subsection 2, {A} a student may enroll in the university, community college, or state college conditionally if the student, or if the student is a minor, the parent or legal guardian of the student, submits a record of immunization stating that the student is in the process of obtaining the required immunizations, and that record shows that the student has made satisfactory progress toward obtaining those immunizations.*

~~{4.}~~5. The university, *community college, and state college* shall retain the proof of immunity on a computerized record or on a form provided by the Division.

~~{5.}~~6. The university, *community college, or state college* shall not refuse to enroll a student because he has not been immunized if the student, or if the student is a minor, the parent or legal guardian of the student, has submitted to the ~~{university}~~ *institution* a written statement indicating that his religious belief prohibits immunizations. The ~~{university}~~ *institution* shall keep the statement on file.

~~{6.}~~7. If the medical condition of a student does not permit him to be immunized to the extent required, the student, or if the student is a minor, the parent or legal guardian of the student, must submit to the ~~{university}~~ *institution* a statement of that fact written by a licensed physician.

The ~~{university}~~ *institution* shall keep the statement on file.

~~{7.}~~8. If additional requirements of immunity are imposed by law after a student has been enrolled in the ~~{university}~~ *institution*, the student, or if the student is a minor, the parent or legal guardian of the student, shall submit an additional proof of immunity to the ~~{university}~~ *institution* stating that the student has met the new requirements of immunity.

~~{8.}~~9. If the health authority determines that, at ~~{the}~~ *a community college, state college, or* university, there is a case having a communicable disease against which immunity is required for admission to the university, and a student who has not submitted proof of immunity to that disease is attending that university, the president of the *institution* ~~{university}~~ shall require that:

(a) The student be immunized; or

(b) The student be excluded from the *institution* ~~{university}~~ until allowed to return by the health authority.

~~{9.}~~10. A student shall not attend a university, *community college, or state college* from which he is excluded until allowed to return by the health authority. The parent or legal guardian of a student, if the student is a minor, shall not allow the student to attend a university, *community college, or state college* from which he is excluded until allowed to return by the health authority.

~~{10.}~~11. Any student who is enrolled in a program of distance education and who does not attend a class on campus is exempt from the requirements of this section.

~~{11.}~~12. As used in this section:

(a) "Postsecondary educational institution" has the meaning ascribed to it in [NRS 394.099](#).



(b) "University" means any university within the Nevada System of Higher Education or any private postsecondary educational institution.

(c) "Community college" means all of the community colleges within the Nevada System of Higher Education.

(d) "State college" means all of the state colleges within the Nevada System of Higher Education.

(e) "Institution" means any university, community college, or state college as described above.

The authority of the State Board of Health to consider and grant a variance from the requirements of a regulation is set forth at NRS 439.200 and NAC 439.200 – 439.280.

Persons wishing to comment upon the proposed variance may appear at the scheduled public hearing or may submit written testimony at least five days before the scheduled hearing to:

Secretary, State Board of Health  
Division of Public and Behavioral Health  
4150 Technology Way, Suite 300  
Carson City, NV 89706

Anyone wishing to testify for more than five minutes on the proposed variance must petition the Board of Health at the above address. Petitions shall contain the following: 1) a concise statement of the subject(s) on which the petitioner will present testimony; 2) the estimated time for the petitioner's presentation.

This notice has also been posted at the following locations:

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH, 4150 TECHNOLOGY WAY, CARSON CITY, NV

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH WEBSITE:

<http://dpbh.nv.gov/Boards/BOH/Meetings/Meetings/>