



# THE LONG-CHAMBERS AEROSPACE SAFETY PROTOCOL INITIATIVE

Post Mandated mRNA Therapy Screening Tool  
for Aviators and Crew

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# BOTTOM LINE UP FRONT

Despite the overwhelming evidence and documented injuries and questionable deaths recently, post roll out of the COVID 19 Vaccination Program and subsequent mandates, serious political debates and stonewalling have only resulted in turning friendly skies into dangerous skies.

For the purpose of this initiative, we shall define “vaccine” as being the biological gene modification agents.

The collective endeavors of world leaders in aviation safety and medical expertise have led to;

1) Creation of the LONG-CHAMBERS AEROSPACE SAFETY PROTOCOL INITIATIVE, effectively screening pilots and crew post COVID vaccines

2) Emphasis on the need to continue the safe and effective practice of self reporting under the voluntary Flight Operational Quality Assurance (FOQA) program.



# ABSTRACT

Safety within professional aviation has vastly improved over the past several decades. This is due in large part to a culture founded upon open communication and self-disclosure of errors or negative safety trends. Consider the voluntary **Flight Operational Quality Assurance (FOQA) program.**

This requires active participation from all flight crew to be effective. Pilots are trained to be careful analysts of their environment, recognizing risks and actively mitigating.

For many, their training and differential risk analysis led to concerns and negative conclusions regarding the compatibility of Covid-19 vaccination with health and flight safety.



# A SOLUTION

**“The practice of medicine is an art, not an algorithm.**

**In the zero-defect environment of aviation medicine, failure is not an option.”**

**LTC (Ret.) Peter Constantine Chambers, D.O.  
Special Operations Flight Surgeon, Green Beret**



# Medical Certification

## THE REGS

### Current COVID 19 Vaccine Considerations

#### AME Guidelines State the Following:

**Do Not Issue.** “AMEs should not issue airmen medical certificates to applicants who are using these or classes of medications.”

**FDA (Food and Drug Administration) approved less than 12 months ago.** The FAA generally requires at least one-year of post-marketing experience with a new drug before consideration for aeromedical certification purposes. This observation period allows time for uncommon, but aeromedically significant, adverse effects to manifest themselves. Contact either your Regional Flight Surgeon or AMCD for guidance on specific applicants or to request consideration for a particular medication

See: [https://www.faa.gov/ame\\_guide/pharm/dni\\_dnf](https://www.faa.gov/ame_guide/pharm/dni_dnf)

# Medical Certification

**THE REGS**

## Current COVID 19 Vaccine Considerations

Individuals holding an FAA-issued Airman Medical Certificate or Medical Clearance are reminded that they are prohibited from performing flight crewmember duties or air traffic control duties if they do not meet medical certification requirements, including those related to adverse events from medications that render them unable to perform such duties.

**14CFR61.53** applies to all certificated pilots whether they hold a medical certificate or not.

AAM continues to monitor the situation and will adjust this policy as necessary to ensure aviation safety.

# Medical Certification

## THE REGS

### Current COVID 19 Vaccine Considerations

The Federal Air Surgeon determined that FAA medical certificate holders may not act as pilot in command, or in any other capacity as a required flightcrew member, for 48 hours after each dose of the Pfizer-BioNTech, Moderna, and Johnson & Johnson vaccines. The Federal Air Surgeon made this determination after evaluation of available medical information about these COVID-19 vaccines and potential side effects. As a result of this determination and consistent with 14 CFR § 61.53(a), each person subject to part 67 who receives the vaccine must wait 48 hours after each dose before acting as pilot in command or as a required flightcrew member.

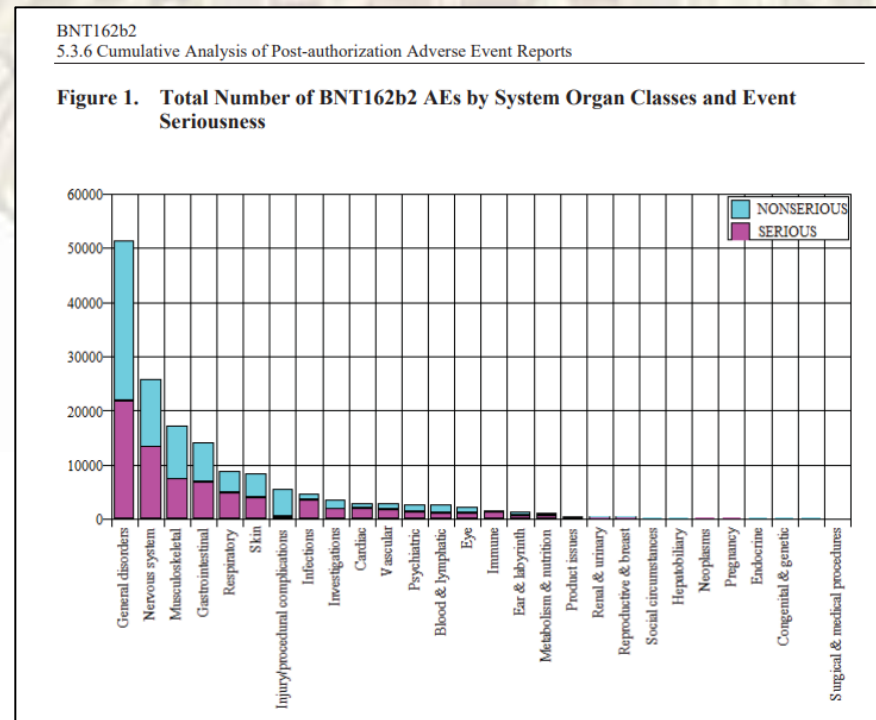
In the event that an FAA medical certificate holder experiences side effects after the 48-hour period has elapsed, the medical certificate holder may not act as pilot in command, or in any other capacity as a required flightcrew member as described at [14 CFR § 61.53\(a\)](#) for the duration of the symptoms.

# Medical Certification

## Current COVID 19 Vaccine Considerations

# THE RISKS

Per Worldwide Safety report issued by Pfizer 28 February 2021, (5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021) cumulative analysis report revealed ADVERSE EVENTS (AE), summarized as follows:





# Medical Certification

## Current COVID 19 Vaccine Considerations

# THE RISKS

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Table 7. AESIs Evaluation for BNT162b2

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
<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 Table 4.
<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>  <b>CARDIOVASCULAR DISORDERS</b>	<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>

# Medical Certification

## Current COVID 19 Vaccine Considerations

# THE RISKS

## ADVERSE EVENTS of SPECIAL INTEREST (AESI), continued:

Table 7. AESIs Evaluation for BNT162b2	
AESIs* Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
	<ul style="list-style-type: none"><li>Relevant event outcome<sup>c</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>d</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>

**ANOSMIA**

**DERMATOLOGIC**

Table 7. AESIs Evaluation for BNT162b2	
AESIs* Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
	<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 haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15);</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>

**BLOOD DISORDERS**

Table 7. AESIs Evaluation for BNT162b2	
AESIs* 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 (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each);</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 (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>d</sup> and Child (1 each);</li><li>Number of relevant events<sup>d</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>

**LIVER DISEASE**

**BELLS PALSY**



# Medical Certification

## Current COVID 19 Vaccine Considerations

# THE RISKS

## ADVERSE EVENTS of SPECIAL INTEREST (AESI), continued:

Table 7. AESIs Evaluation for BNT162b2	
AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
<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>	<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: 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>F</sup>; Chronic fatigue syndrome; Polyarthrits; 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), Polyarthrits (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>

### IMMUNITY DISORDERS

### MUSCULO-SKELETAL DISORDERS

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>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 (&gt;9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries.</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 (&gt;2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each);</li><li>Relevant event onset latency (n = 423): Range from &lt;24 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 (&gt; 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries;</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>

### NEUROLOGICAL DISORDERS

Table 7. AESIs Evaluation for BNT162b2	
AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
<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 (&gt;6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each);</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>	For relevant cases, please refer to Table 6, Description of Missing Information, <i>Use in Pregnancy and While Breast Feeding</i>
<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>

### KIDNEY DISORDERS

# Medical Certification

## Current COVID 19 Vaccine Considerations

# THE RISKS

## ADVERSE EVENTS of SPECIAL INTEREST (AESI), continued:

Table 7. AESIs Evaluation for BNT162b2	
AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
<i>(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome</i>	<ul style="list-style-type: none"><li>• Countries of incidence: United Kingdom (70), 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' 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>
<b>RESPIRATORY DISORDERS</b>	
<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>	<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>
<b>CLOTting DISORDERS / PULMONARY EMBOLI</b>	
<b>Stroke</b> <i>Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents</i>	<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	
AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases (N=42086)
<i>(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)</i>	<ul style="list-style-type: none"><li>• Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries;</li><li>• Subjects' gender (n= 273): female (182), male (91);</li><li>• Subjects' age group (n=265): Adult (59), Elderly (205), Child<sup>a</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 Lacunar 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>CEREBRO-VASCULAR DISORDERS</b>	
<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>
<b>VENOUS DISORDERS</b>	

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>a. For the complete list of the AESIs, please refer to Appendix 5;</li><li>b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;</li><li>c. Subjects with age ranged between 18 and 64 years;</li><li>d. Subjects with age equal to or above 65 years;</li><li>e. Subjects with age ranged between 2 and 11 years;</li><li>f. Subjects with age ranged between 12 and less than 18 years;</li><li>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;</li><li>h. Subjects with age ranged between 1 (28 days) and 23 months;</li><li>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;</li><li>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;</li><li>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;</li><li>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</li><li>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.</li><li>n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;</li></ul>



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## Current COVID 19 Vaccine Considerations

# THE RISKS

### LIST OF 1291 ADVERSE EVENTS OF SPECIAL INTEREST (Released by Pfizer under FOIA):

**Ip36 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;Anti-gliadin 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

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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;Bromsulphthalein 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;Cerebellar 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

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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;Cryofibrinogenemia;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;Embolus;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

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## Current COVID 19 Vaccine Considerations

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### LIST OF 1291 ADVERSE EVENTS OF SPECIAL INTEREST (Released by Pfizer under FOIA):

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;Felt's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foeter 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-Schönlein purpura;Henoch-Schönlein 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 meningoencephalitis;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

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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;Herpetetic 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;Hypertransaminaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothénar 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 blennorrhagica;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 planilaris;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

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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;Herpetetic 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;Hypertransaminaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothénar 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 blennorrhagica;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 planilaris;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

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## Current COVID 19 Vaccine Considerations

# THE RISKS

### LIST OF 1291 ADVERSE EVENTS OF SPECIAL INTEREST (Released by Pfizer under FOIA):

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;Paraneoplastic 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 influenza;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

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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;Spleen artery thrombosis;Spleen embolism;Spleen thrombosis;Spleen 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

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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 1 hypersensitivity;Type III immune complex mediated reaction;Uthoff'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;Vesicular venous thrombosis;Vlth nerve paralysis;Vlth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;Xlth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

**PFIZER REPORTED 1291  
ADVERSE EVENTS of  
SPECIAL INTEREST**

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## Medical Certification and Disability Current COVID 19 Vaccine Considerations

If you are sick or injured by the vaccines or for any other reason and remain so for 6 months or more, then you are probably protected against discrimination per the Americans with Disabilities Act or Rehabilitation Act of 1973

Anti-discrimination provisions prohibit employers from reprimanding, punishing or terminating employees based on their disability

Employers must provide Reasonable Accommodation to disabled employees, whether they are contracted or engaged full or part-time and regardless of the cause of their disability.

See: <https://www.ada.gov/pubs/adastatute08.htm>





# SUMMARY

Many aviation professionals also sought guidance from civil aviation regulators. These regulators are ultimately responsible for the safe and secure transport of people, yet most if not all actively ignored their own safety recommendations against unproven, unapproved drug use by flight crews. Transport Canada, for instance, simply removed this online guidance the week following numerous written and pointed questions regarding same. Once airlines mandated vaccination, many pilots steadfastly refused based on risk and were subsequently put on unpaid leave or outright terminated. Principled professionals were forced out of aviation and the industry lost hundreds of thousands of hours of experience. Now, the global airline industry is heading into a dire staffing crisis.

Thousands of other pilots were coerced into vaccination to provide for their families. This has taken a toll on their mental health and performance. As sobering as all of this is, it merely set the stage for what we are now witnessing: a landscape which should greatly concern airlines and the travelling public.



# SUMMARY

Scientists and doctors are hearing daily from hundreds of vaccine-injured airline pilots. These harms include cardiovascular issues, blood clots, neurological and auditory issues, to name just a few. Many of our pilots have lost medical certification to fly and may not recover the same. Others are continuing to pilot aircraft while carrying symptoms that should be declared and investigated, creating a human factors hazard of unprecedented breadth.

The very foundation of the commercial aviation culture - non-punitive reporting - no longer exists. Aviation professionals have suffered and are suffering medical issues that appear to correlate to receipt of Covid-19 vaccinations. Their current spectrum of symptoms is broad, ranging nuisance to death and some adverse reactions may only manifest over time. There have been no long-term studies on any of these shots; vaccine health risks, clinical trial fraud, poor practice and insignificant efficacy continues to mount.



# SUMMARY

The Pfizer documents released under FOIA combined with FDA, MHRA and EMA regulatory documentation show that essential safety and efficacy information has been withheld from the public, and that the scope of regulatory oversight and testing requirements is inadequate. Worse, there appears to be no evidence of aviation regulators, airlines or unions having performed any of their own due diligence into Covid-19 vaccines and the impact on aviator or crew health or performance. This is at complete odds with existing aviation medical standards.

Questions exist around competence and possible negligence. Failure to address this potential medical watershed will make the airlines and unions complicit in a culture shift that has rocked the aviation mantra of “safety first, always”. The airlines and unions represented have been encouraged to assist and warned of dire repercussions, repeatedly.

To date there has been little meaningful action, and in many cases nothing but stone-walling and silence.

There is a saying in aviation, “If there’s doubt, there is no doubt.” New data raises significant concerns over the safety or efficacy of the Covid-19 vaccines and their long-term effects. There should therefore be no further doubt in aviation. Safety must return to the fore.



# CALL TO ACTION

Civil aviation authorities such as the Federal Aviation Administration, Transport Canada, UK Civil Aviation Authority and European Union Aviation Safety Agency must begin fulfilling their regulatory obligations.

The crisis in pilot health must be publicly addressed by airlines and representing unions.

This is a CALL TO ACTION FOR:

- Where it exists, mandated Covid-19 vaccination for aviation workers **must cease**. At the minimum, a **SAFETY HOLD** must be mandated to institute this **AEROSPACE SAFETY PROTOCOL INITIATIVE**, which screens all medical certificate holders (including controllers) to ensure they have not suffered vaccine injuries.
- A permissive environment for self-reporting (SEE AC 120-82) needs to be reemphasized by regulators and airlines.
- Pro-active investigation through medical screening of pilots and cabin crew needs to be a high priority, focusing on high prevalence side effects which are now showing up in the general public and in many of our vaccinated aviation professionals.
- Airlines and regulators hold data about sickness and medical certificate suspension, including symptoms and causal reasons. This data should be analyzed by independent third parties to establish or rule out Covid-19 vaccination as a possible cause.



# SCREENING PROCESS

(Examples of symptoms-based and pro-active screening process)

**CLINICAL SYMPTOMS:** dizziness, vertigo, impaired balance

**WORK UP:** CT Temporal Bone, high-resolution, 3 Tesla MRI brain, with and without contrast, WITH Internal Auditory Canal (IAC) - Protocol and attention to posterior fossa structures, **INFLAMMATORY MARKERS** - CRP-hs Fibrinogen D-Dimer

**ADDITIONAL (Per Findings):** Neuro Consult post findings of Neuroradiologist

**CLINICAL SYMPTOMS:** chest pain, palpitations, arrhythmias

**WORK UP:** Cardiac MRI for morphology and function, with late-phase gadolinium enhancement to assess for myocarditis, pericarditis, EKG, **INFLAMMATORY MARKERS** - CRP-hs Fibrinogen D-Dimer Troponin-1

**ADDITIONAL (Per Findings):** Cardiology Consult

**CLINICAL SYMPTOMS:** shortness of breath, dyspnea on exertion

**WORK UP:** CT Angiogram of Lung with arterial and venous phases to evaluate for peripheral microthrombi and/or larger pulmonary emboli, **INFLAMMATORY MARKERS** - CRP-hs Fibrinogen D-Dimer

**ADDITIONAL (Per Findings):** Internal Medicine, Pulmonology Consult

# OTHER CONSIDERATIONS FOR SCREENING

(When required per initial findings)

- Comprehensive Metabolic Profile Cholesterol profile
- Glycosylated hemoglobin Fasting insulin
- CBC with differential Vitamin B12, Folate
- Vitamin B6 and B1 25-OH Vitamin D
- Magnesium (serum and RBC) Zinc
- ENDOCRINE TESTS - Draw in AM prior to any meds to assess damage to endocrine system
- FSH, LH, Estradiol, Progesterone, Testosterone (free and total), DHEA-S, DHEA
- TSH (hs), Free T3 and Free T4, Anti-microsomal, Anti-thyroglobulin AB
- 8 AM Cortisol, total and free, Prolactin, Parathyroid Hormone, Amylase, Lipase
- PSA, CA125, CA 19-9, CEA, CA 15-9
- INFLAMMATORY MARKERS and SPECIALTY TESTS:
- CRP-hs Fibrinogen D-Dimer Troponin-1
- Ferritin Cytokine Panel IL-6, IL-10 Myeloperoxidase (MPO)
- 24-hour urine for measure of: catecholamines, metanephrines, VMA
- To assess new infections:
- SARS-CoV-2 spike protein antibodies
- SARS-CoV-2 Nucleocapsid Antibodies
- Mycoplasma pneumoniae, EBV titers, CMV titers, RSV titers
- HIV and other viral titers as indicated by presenting symptoms.
- G6PD

# SOURCES and REFERENCES

The COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol

<https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-2021.pdf>

[https://www.faa.gov/ame\\_guide/pharm/dni\\_dnf](https://www.faa.gov/ame_guide/pharm/dni_dnf)

[750+ Studies About the Dangers of the COVID-19 Injections](#)

TRUTH FOR HEALTH VACCINE INJURY TREATMENT GUIDE.

<https://www.truthforhealth.org/2022/04/vaccine-injury-treatment-guide-your-roadmap-to-recovery/>

GLOBAL COALITION STATEMENT: COMMERCIAL PILOT VACCINE INJURIES.

<https://gaacoalition.substack.com/>

LTC Theresa M. Long, MD, MPH, FS

<https://rumble.com/voz7ik-theresa-long-md-mp-h-the-vaccine-is-a-greater-threat-to-soldiers-and-defense.html>

**DMED Data**


<https://www.youtube.com/watch?v=Lt7QzetfRSQ>

NEAR MISS – Vaccine Injured Pilot

<https://rumble.com/voz514-cody-flint-i-have-missed-an-entire-year-of-my-life-trapped-in-vaccine-injur.html>

<https://www.ada.gov/pubs/adastatute08.htm>

[https://www.faa.gov/documentLibrary/media/Advisory\\_Circular/AC\\_120-82.pdf](https://www.faa.gov/documentLibrary/media/Advisory_Circular/AC_120-82.pdf)

 U.S. Department of Transportation  Federal Aviation Administration	<b>Advisory Circular</b>	
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Subject: FLIGHT OPERATIONAL QUALITY ASSURANCE	Date: 4/12/04 Initiated By: AFS-230	AC No: 120-82 Change:
<hr/>		
<p><b>1. PURPOSE.</b> This advisory circular (AC) provides guidance on one means, but not necessarily the only means, of developing, implementing, and operating a voluntary Flight Operational Quality Assurance (FOQA) program that is acceptable to the Federal Aviation Administration (FAA).</p> <p><b>a.</b> FOQA is a voluntary safety program that is designed to make commercial aviation safer by allowing commercial airlines and pilots to share de-identified aggregate information with the FAA so that the FAA can monitor national trends in aircraft operations and target its resources to address operational risk issues (e.g., flight operations, air traffic control (ATC), airports). The fundamental objective of this new FAA/pilot/carrier partnership is to allow all three parties to identify and reduce or eliminate safety risks, as well as minimize deviations from the regulations. To achieve this objective and obtain valuable safety information, the airlines, pilots, and the FAA are voluntarily agreeing to participate in this program so that all three organizations can achieve a mutual goal of making air travel safer.</p> <p><b>b.</b> A cornerstone of this new program is the understanding that aggregate data that is provided to the FAA will be kept confidential and the identity of reporting pilots or airlines will remain anonymous as allowed by law. Information submitted to the FAA pursuant to this program will be protected as "voluntarily submitted safety related data" under Title 14 of the Code of Federal Regulations (14 CFR) part 193.</p> <p>(1) In general, aggregate FOQA data provided to the FAA under 14 CFR part 13, section 13.401 should be stripped of information that could identify the submitting airline prior to leaving the airline premises and, regardless of submission venue, should include the following statement:</p> <p><b>WARNING: This FOQA information is protected from disclosure under 49 U.S.C. 40123 and part 193. It may be released only with the written permission of the Federal Aviation Administration Associate Administrator for Regulation and Certification.</b></p>		



# CONCLUSION

Today, we have a unique opportunity to salvage our aviation industry and traveling society through local action in defiance of political appointees and myopic federal policy-makers who refuse to recognize the consequences of their illegal 'vaccine' mandates; which have injured or killed millions of people around the world. Worse, the evidence is now abundantly clear that all of these shots were experimental, rushed and ill-advised, even by the FDA's internal review committee prior to the Emergency Use Authorization.

Given that our governments have failed in their obligations to protect their citizens and in some cases, participated in the genocide in progress, our only solution is for each of us to help others by applying common sense collaboration and using the laws already in existence to preserve the enormous commercial, private and national security tool that we all call the aviation industry.

We are not getting any help from any government and we're not going to. Our safety and our destiny is in our hands to preserve our society, life and way of living. We must all collaborate to identify the risks, help people mitigate those risks and get the aviation community back into full operation as it was prior to Covid.

Collaboration among all interested parties is the key and even the flying public can help by insisting on these safety measures and demanding that airlines ensure at least one un-vaccinated pilot is on every flight; and with access to the controls of the aircraft. Sitting behind a locked cockpit door will not help when there is an in-flight emergency.

Medical Certificate holders are already facing recurrent certifications by their respective flight surgeons and this collaborative effort is designed to help vaccine-injured people understand their risks, repair their injuries and keep our society, goods and services freely moving around the world



# QUESTIONS

CDC, NIH, Pharmaceutical Profits →

FDA, FAA, AMEs →

Fear, Political Pressure to Conform →

Violation of Do Not Issue policy →

Organizational Influences

Unsafe Supervision

Preconditions

Unsafe Acts

**Accident!**

