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FOIA Release – 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports: EXPLOSIVE List of 100s of known adverse events for the Pfizer CoV-2 Injections

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**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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**5.3.6 Cumulative Analysis
of Post-authorization
Adverse Event Reports**

**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 anti-
body positive
Anti-glomerular basement membrane dis-
ease
Anti-glycyl-tRNA synthetase antibody posi-
tive
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	Arterial thrombosis
Anti-muscle specific kinase antibody positive	Arteriovenous fistula thrombosis
Anti-myelin-associated glycoprotein antibodies positive	Arteriovenous graft site stenosis
Anti-myelin-associated glycoprotein associated polyneuropathy	Arteriovenous graft thrombosis
Antimyocardial antibody positive	Arteritis
Anti-neuronal antibody positive	Arteritis coronary
Antineutrophil cytoplasmic antibody increased	Arthralgia
Antineutrophil cytoplasmic antibody positive	Arthritis
Anti-neutrophil cytoplasmic antibody positive vasculitis	Arthritis enteropathic
Anti-NMDA antibody positive	Ascites
Antinuclear antibody increased	Aseptic cavernous sinus thrombosis
Antinuclear antibody positive	Aspartate aminotransferase abnormal
Antiphospholipid antibodies positive	Aspartate aminotransferase increased
Antiphospholipid syndrome	Aspartate-glutamate-transporter deficiency
Anti-platelet antibody positive	AST to platelet ratio index increased
Anti-prothrombin antibody positive	AST/ALT ratio abnormal
Antiribosomal P antibody positive	Asthma
Anti-RNA polymerase III antibody positive	Asymptomatic COVID- 19
Anti-saccharomyces cerevisiae antibody test positive	Ataxia
Anti-sperm antibody positive	Atheroembolism
Anti-SRP antibody positive	Atonic seizures
Antisynthetase syndrome	Atrial thrombosis
Anti-thyroid antibody positive	Atrophic thyroiditis
Anti-transglutaminase antibody increased	Atypical benign partial epilepsy
Anti-VGCC antibody positive	Atypical pneumonia
Anti- VGKC antibody positive	Aura;Autoantibody positive
Anti-vimentin antibody positive	Autoimmune anaemia
Antiviral prophylaxis	Autoimmune aplastic anaemia
Antiviral treatment	Autoimmune arthritis
Anti-zinc transporter 8 antibody positive	Autoimmune blistering disease
Aortic embolus	Autoimmune cholangitis
Aortic thrombosis	Autoimmune colitis
Aortitis	Autoimmune demyelinating disease
Aplasia pure red cell	Autoimmune dermatitis
Aplastic anaemia	Autoimmune disorder
Application site thrombosis	Autoimmune encephalopathy
Application site vasculitis	Autoimmune endocrine disorder
Arrhythmia	Autoimmune enteropathy
Arterial bypass occlusion	Autoimmune eye disorder
Arterial bypass thrombosis	Autoimmune haemolytic anaemia
	Autoimmune heparin-induced thrombocytopenia
	Autoimmune hepatitis
	Autoimmune hyperlipidaemia
	Autoimmune hypothyroidism

Autoimmune inner ear disease	Blood alkaline phosphatase abnormal
Autoimmune lung disease	Blood alkaline phosphatase increased
Autoimmune lymphoproliferative syndrome	Blood bilirubin abnormal
Autoimmune myocarditis	Blood bilirubin increased
Autoimmune myositis	Blood bilirubin unconjugated increased
Autoimmune nephritis	Blood cholinesterase abnormal
Autoimmune neuropathy	Blood cholinesterase decreased
Autoimmune neutropenia	Blood pressure decreased
Autoimmune pancreatitis	Blood pressure diastolic decreased
Autoimmune pancytopenia	Blood pressure systolic decreased
Autoimmune pericarditis	Blue toe syndrome
Autoimmune retinopathy	Brachiocephalic vein thrombosis
Autoimmune thyroid disorder	Brain stem embolism
Autoimmune thyroiditis	Brain stem thrombosis
Autoimmune uveitis	Bromosulphthalein test abnormal
Autoinflammation with infantile enterocolitis	Bronchial oedema
Autoinflammatory disease	Bronchitis
Automatism epileptic	Bronchitis mycoplasmal
Autonomic nervous system imbalance	Bronchitis viral
Autonomic seizure	Bronchopulmonary aspergillosis allergic
Axial spondyloarthritis	Bronchospasm
Axillary vein thrombosis	Budd-Chiari syndrome
Axonal and demyelinating polyneuropathy	Bulbar palsy
Axonal neuropathy;Bacterascites	Butterfly rash
Baltic myoclonic epilepsy	C1q nephropathy
Band sensation	Caesarean section
Basedow's disease	Calcium embolism
Basilar artery thrombosis	Capillaritis
Basophilopenia;B-cell aplasia	Caplan's syndrome
Behcet's syndrome	Cardiac amyloidosis
Benign ethnic neutropenia	Cardiac arrest
Benign familial neonatal convulsions	Cardiac failure
Benign familial pemphigus	Cardiac failure acute
Benign rolandic epilepsy	Cardiac sarcoidosis
Beta-2 glycoprotein antibody positive	Cardiac ventricular thrombosis
Bickerstaff's encephalitis	Cardiogenic shock
Bile output abnormal	Cardiolipin antibody positive
Bile output decreased	Cardiopulmonary failure
Biliary ascites	Cardio-respiratory arrest
Bilirubin conjugated abnormal	Cardio-respiratory distress
Bilirubin conjugated increased	Cardiovascular insufficiency
Bilirubin urine present	Carotid arterial embolus
Biopsy liver abnormal	Carotid artery thrombosis
Biotinidase deficiency	Cataplexy
Birdshot chorioretinopathy	Catheter site thrombosis

Catheter site vasculitis	Clonic convulsion
Cavernous sinus thrombosis	Coeliac disease
CDKL5 deficiency disorder	Cogan's syndrome
CEC syndrome	Cold agglutinins positive
Cement embolism	Cold type haemolytic anaemia
Central nervous system lupus	Colitis
Central nervous system vasculitis	Colitis erosive
Cerebellar artery thrombosis	Colitis herpes
Cerebellar embolism	Colitis microscopic
Cerebral amyloid angiopathy	Colitis ulcerative
Cerebral arteritis	Collagen disorder
Cerebral artery embolism	Collagen-vascular disease
Cerebral artery thrombosis	Complement factor abnormal
Cerebral gas embolism	Complement factor C1 decreased
Cerebral microembolism	Complement factor C2 decreased
Cerebral septic infarct	Complement factor C3 decreased
Cerebral thrombosis	Complement factor C4 decreased
Cerebral venous sinus thrombosis	Complement factor decreased
Cerebral venous thrombosis	Computerised tomogram liver abnormal
Cerebrospinal thrombotic tamponade	Concentric sclerosis
Cerebrovascular accident	Congenital anomaly
Change in seizure presentation	Congenital bilateral perisylvian syndrome
Chest discomfort	Congenital herpes simplex infection
Child-Pugh-Turcotte score abnormal	Congenital myasthenic syndrome
Child-Pugh-Turcotte score increased	Congenital varicella infection
Chillblains	Congestive hepatopathy
Choking	Convulsion in childhood
Choking sensation	Convulsions local
Cholangitis sclerosing	Convulsive threshold lowered
Chronic autoimmune glomerulonephritis	Coombs positive haemolytic anaemia
Chronic cutaneous lupus erythematosus	Coronary artery disease
Chronic fatigue syndrome	Coronary artery embolism
Chronic gastritis	Coronary artery thrombosis
Chronic inflammatory demyelinating polyradiculoneuropathy	Coronary bypass thrombosis
Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids	Coronavirus infection
Chronic recurrent multifocal osteomyelitis	Coronavirus test
Chronic respiratory failure	Coronavirus test negative
Chronic spontaneous urticaria	Coronavirus test positive
Circulatory collapse	Corpus callosotomy
Circumoral oedema	Cough
Circumoral swelling	Cough variant asthma
Clinically isolated syndrome	COVID-19
	COVID-19 immunisation
	COVID-19 pneumonia
	COVID-19 prophylaxis

COVID-19 treatment
Cranial nerve disorder
Cranial nerve palsies multiple
Cranial nerve paralysis
CREST syndrome
Crohn's disease
Cryofibrinogenaemia
Cryoglobulinaemia
CSF oligoclonal band present
CSWS syndrome
Cutaneous amyloidosis
Cutaneous lupus erythematosus
Cutaneous sarcoidosis
Cutaneous vasculitis
Cyanosis
Cyclic neutropenia
Cystitis interstitial
Cytokine release syndrome
Cytokine storm
De novo purine synthesis inhibitors associated acute inflammatory syndrome
Death neonatal
Deep vein thrombosis
Deep vein thrombosis postoperative
Deficiency of bile secretion
Deja vu
Demyelinating polyneuropathy
Demyelination
Dermatitis
Dermatitis bullous
Dermatitis herpetiformis
Dermatomyositis
Device embolisation
Device related thrombosis
Diabetes mellitus
Diabetic ketoacidosis
Diabetic mastopathy
Dialysis amyloidosis
Dialysis membrane reaction
Diastolic hypotension
Diffuse vasculitis
Digital pitting scar
Disseminated intravascular coagulation
Disseminated intravascular coagulation in newborn

Disseminated neonatal herpes simplex
Disseminated varicella
Disseminated varicella zoster vaccine virus infection
Disseminated varicella zoster virus infection
DNA antibody positive; Double cortex syndrome
Double stranded DNA antibody positive
Dreamy state
Dressler's syndrome
Drop attacks
Drug withdrawal convulsions
Dyspnoea
Early infantile epileptic encephalopathy with burst-suppression
Eclampsia
Eczema herpeticum
Embolia cutis medicamentosa
Embolic cerebellar infarction
Embolic cerebral infarction
Embolic pneumonia
Embolic stroke
Embolism
Embolism arterial
Embolism venous
Encephalitis
Encephalitis allergic
Encephalitis autoimmune
Encephalitis brain stem
Encephalitis haemorrhagic
Encephalitis periaxialis diffusa
Encephalitis post immunisation
Encephalomyelitis
Encephalopathy
Endocrine disorder
Endocrine ophthalmopathy
Endotracheal intubation
Enteritis
Enteritis leukopenic
Enterobacter pneumonia
Enterocolitis
Enteropathic spondylitis
Eosinopenia
Eosinophilic fasciitis
Eosinophilic granulomatosis with polyangiitis

Eosinophilic oesophagitis
Epidermolysis
Epilepsy
Epilepsy surgery
Epilepsy with myoclonic-atonic seizures
Epileptic aura
Epileptic psychosis
Erythema
Erythema induratum
Erythema multiforme
Erythema nodosum
Evans syndrome
Exanthema subitum
Expanded disability status scale score decreased
Expanded disability status scale score increased
Exposure to communicable disease
Exposure to SARS-CoV-2
Eye oedema
Eye pruritus
Eye swelling
Eyelid oedema
Face oedema
Facial paralysis
Facial paresis
Faciobrachial dystonic seizure
Fat embolism
Febrile convulsion
Febrile infection-related epilepsy syndrome
Febrile neutropenia
Felty's syndrome
Femoral artery embolism
Fibrillary glomerulonephritis
Fibromyalgia
Flushing
Foaming at mouth
Focal cortical resection
Focal dyscognitive seizures
Foetal distress syndrome
Foetal placental thrombosis
Foetor hepaticus
Foreign body embolism
Frontal lobe epilepsy
Fulminant type 1 diabetes mellitus

Galactose elimination capacity test abnormal
Galactose elimination capacity test decreased
Gamma-glutamyltransferase abnormal
Gamma-glutamyltransferase increased
Gastritis herpes
Gastrointestinal amyloidosis
Gelastic seizure
Generalised onset non-motor seizure
Generalised tonic-clonic seizure
Genital herpes
Genital herpes simplex
Genital herpes zoster
Giant cell arteritis
Glomerulonephritis
Glomerulonephritis membranoproliferative
Glomerulonephritis membranous
Glomerulonephritis rapidly progressive
Glossopharyngeal nerve paralysis
Glucose transporter type 1 deficiency syndrome
Glutamate dehydrogenase increased
Glycocholic acid increased
GM2 gangliosidosis
Goodpasture's syndrome
Graft thrombosis
Granulocytopenia
Granulocytopenia neonatal
Granulomatosis with polyangiitis
Granulomatous dermatitis
Grey matter heterotopia
Guanase increased
Guillain-Barre syndrome
Haemolytic anaemia
Haemophagocytic lymphohistiocytosis
Haemorrhage
Haemorrhagic ascites
Haemorrhagic disorder
Haemorrhagic pneumonia
Haemorrhagic varicella syndrome
Haemorrhagic vasculitis
Hantavirus pulmonary infection
Hashimoto's encephalopathy
Hashitoxicosis
Hemimegalencephaly
Henoch-Schonlein purpura

Henoch-Schonlein purpura nephritis
Hepaplastin abnormal
Hepaplastin decreased
Heparin-induced thrombocytopenia
Hepatic amyloidosis
Hepatic artery embolism
Hepatic artery flow decreased
Hepatic artery thrombosis
Hepatic enzyme abnormal
Hepatic enzyme decreased
Hepatic enzyme increased
Hepatic fibrosis marker abnormal
Hepatic fibrosis marker increased
Hepatic function abnormal
Hepatic hydrothorax
Hepatic hypertrophy
Hepatic hypoperfusion
Hepatic lymphocytic infiltration
Hepatic mass
Hepatic pain
Hepatic sequestration
Hepatic vascular resistance increased
Hepatic vascular thrombosis
Hepatic vein embolism
Hepatic vein thrombosis
Hepatic venous pressure gradient abnormal
Hepatic venous pressure gradient increased
Hepatitis;Hepatobiliary scan abnormal
Hepatomegaly
Hepatosplenomegaly
Hereditary angioedema with C1 esterase inhibitor deficiency
Herpes dermatitis
Herpes gestationis
Herpes oesophagitis
Herpes ophthalmic
Herpes pharyngitis
Herpes sepsis
Herpes simplex
Herpes simplex cervicitis
Herpes simplex colitis
Herpes simplex encephalitis
Herpes simplex gastritis
Herpes simplex hepatitis
Herpes simplex meningitis

Herpes simplex meningoencephalitis
Herpes simplex meningomyelitis
Herpes simplex necrotising retinopathy
Herpes simplex oesophagitis
Herpes simplex otitis externa
Herpes simplex pharyngitis
Herpes simplex pneumonia
Herpes simplex reactivation
Herpes simplex sepsis
Herpes simplex viraemia
Herpes simplex virus conjunctivitis neonatal
Herpes simplex visceral
Herpes virus infection
Herpes zoster
Herpes zoster cutaneous disseminated
Herpes zoster infection neurological
Herpes zoster meningitis
Herpes zoster meningoencephalitis
Herpes zoster meningomyelitis
Herpes zoster meningoradiculitis
Herpes zoster necrotising retinopathy
Herpes zoster oticus
Herpes zoster pharyngitis
Herpes zoster reactivation
Herpetic radiculopathy
Histone antibody positive
Hoigne's syndrome
Human herpesvirus 6 encephalitis
Human herpesvirus 6 infection
Human herpesvirus 6 infection reactivation
Human herpesvirus 7 infection
Human herpesvirus 8 infection
Hyperammonaemia
Hyperbilirubinaemia
Hypercholia
Hypergammaglobulinaemia benign monoclonal
Hyperglycaemic seizure
Hypersensitivity
Hypersensitivity vasculitis
Hyperthyroidism
Hypertransaminasaemia
Hyperventilation
Hypoalbuminaemia
Hypocalcaemic seizure

Hypogammaglobulinaemia
Hypoglossal nerve paralysis
Hypoglossal nerve paresis
Hypoglycaemic seizure
Hyponatraemic seizure
Hypotension
Hypotensive crisis
Hypothenar hammer syndrome
Hypothyroidism
Hypoxia
Idiopathic CD4 lymphocytopenia
Idiopathic generalised epilepsy
Idiopathic interstitial pneumonia
Idiopathic neutropenia
Idiopathic pulmonary fibrosis
IgA nephropathy
IgM nephropathy
IIIrd nerve paralysis
IIIrd nerve paresis
Iliac artery embolism
Immune thrombocytopenia
Immune-mediated adverse reaction
Immune-mediated cholangitis
Immune-mediated cholestasis
Immune-mediated cytopenia
Immune-mediated encephalitis
Immune-mediated encephalopathy
Immune-mediated endocrinopathy
Immune-mediated enterocolitis
Immune-mediated gastritis
Immune-mediated hepatic disorder
Immune-mediated hepatitis
Immune-mediated hyperthyroidism
Immune-mediated hypothyroidism
Immune-mediated myocarditis
Immune-mediated myositis
Immune-mediated nephritis
Immune-mediated neuropathy
Immune-mediated pancreatitis
Immune-mediated pneumonitis
Immune-mediated renal disorder
Immune-mediated thyroiditis
Immune-mediated uveitis
Immunoglobulin G4 related disease
Immunoglobulins abnormal

Implant site thrombosis
Inclusion body myositis
Infantile genetic agranulocytosis
Infantile spasms
Infected vasculitis
Infective thrombosis
Inflammation
Inflammatory bowel disease
Infusion site thrombosis
Infusion site vasculitis
Injection site thrombosis
Injection site urticaria
Injection site vasculitis
Instillation site thrombosis
Insulin autoimmune syndrome
Interstitial granulomatous dermatitis
Interstitial lung disease
Intracardiac mass
Intracardiac thrombus
Intracranial pressure increased
Intrapericardial thrombosis
Intrinsic factor antibody abnormal
Intrinsic factor antibody positive
IPEX syndrome
Irregular breathing
IRVAN syndrome
IVth nerve paralysis
IVth nerve paresis
JC polyomavirus test positive
JC virus CSF test positive
Jeavons syndrome
Jugular vein embolism
Jugular vein thrombosis
Juvenile idiopathic arthritis
Juvenile myoclonic epilepsy
Juvenile polymyositis
Juvenile psoriatic arthritis
Juvenile spondyloarthritis
Kaposi sarcoma inflammatory cytokine syndrome
Kawasaki's disease
Kayser-Fleischer ring
Keratoderma blenorrhagica
Ketosis-prone diabetes mellitus
Kounis syndrome

Lafora's myoclonic epilepsy
Lambl's excrescences
Laryngeal dyspnoea
Laryngeal oedema
Laryngeal rheumatoid arthritis
Laryngospasm
Laryngotracheal oedema
Latent autoimmune diabetes in adults
LE cells present
Lemierre syndrome
Lennox-Gastaut syndrome
Leucine aminopeptidase increased
Leukoencephalomyelitis
Leukoencephalopathy
Leukopenia
Leukopenia neonatal
Lewis-Sumner syndrome
Lhermitte's sign
Lichen planopilaris
Lichen planus
Lichen sclerosus
Limbic encephalitis
Linear IgA disease
Lip oedema;
ip 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	Partial seizures with secondary generalisation
Ocular sarcoidosis	Patient isolation
Ocular vasculitis	Pelvic venous thrombosis
Oculofacial paralysis	Pemphigoid
Oedema	Pemphigus;
Oedema blister	Penile vein thrombosis
Oedema due to hepatic disease	Pericarditis
Oedema mouth	Pericarditis lupus
Oesophageal achalasia	Perihepatic discomfort
Ophthalmic artery thrombosis	Periorbital oedema
Ophthalmic herpes simplex	Periorbital swelling
Ophthalmic herpes zoster	Peripheral artery thrombosis
Ophthalmic vein thrombosis	Peripheral embolism
Optic neuritis	Peripheral ischaemia
Optic neuropathy	Peripheral vein thrombus extension
Optic perineuritis	Periportal oedema
Oral herpes	Peritoneal fluid protein abnormal
Oral lichen planus	Peritoneal fluid protein decreased
Oropharyngeal oedema	Peritoneal fluid protein increased
Oropharyngeal spasm	Peritonitis lupus
Oropharyngeal swelling	Pernicious anaemia
Osmotic demyelination syndrome	Petit mal epilepsy
Ovarian vein thrombosis	Pharyngeal oedema
Overlap syndrome	Pharyngeal swelling
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	Pityriasis lichenoides et varioliformis acuta
Paget-Schroetter syndrome	Placenta praevia
Palindromic rheumatism	Pleuroparenchymal fibroelastosis
Palisaded neutrophilic granulomatous dermatitis	Pneumobilia
Palmoplantar keratoderma	Pneumonia
Palpable purpura	Pneumonia adenoviral
Pancreatitis	Pneumonia cytomegaloviral
Panencephalitis	Pneumonia herpes viral
Papillophlebitis	Pneumonia influenzal
Paracancerous pneumonia	Pneumonia measles
Paradoxical embolism	Pneumonia mycoplasmal
Parainfluenzae viral laryngotracheobronchitis	Pneumonia necrotising
Paraneoplastic dermatomyositis	Pneumonia parainfluenzae viral
Paraneoplastic pemphigus	Pneumonia respiratory syncytial viral
Paraneoplastic thrombosis;	Pneumonia viral
Paresis cranial nerve	POEMS syndrome
Parietal cell antibody positive	Polyarteritis nodosa
Paroxysmal nocturnal haemoglobinuria	Polyarthrititis
Partial seizures;	Polychondritis
	Polyglandular autoimmune syndrome type I
	Polyglandular autoimmune syndrome type II

Polyglandular autoimmune syndrome type III	Product distribution issue
Polyglandular disorder	Product supply issue
Polymicrogyria	Progressive facial hemiatrophy
Polymyalgia rheumatica	Progressive multifocal leukoencephalopathy
Polymyositis	Progressive multiple sclerosis;
Polyneuropathy	Progressive relapsing multiple sclerosis
Polyneuropathy idiopathic progressive	Prosthetic cardiac valve thrombosis
Portal pyaemia	Pruritus
Portal vein embolism	Pruritus allergic
Portal vein flow decreased	Pseudovasculitis
Portal vein pressure increased	Psoriasis
Portal vein thrombosis	Psoriatic arthropathy
Portosplenomesenteric venous thrombosis	Pulmonary amyloidosis
Post procedural hypotension	Pulmonary artery thrombosis
Post procedural pneumonia;	Pulmonary embolism
Post procedural pulmonary embolism	Pulmonary fibrosis
Post stroke epilepsy	Pulmonary haemorrhage
Post stroke seizure	Pulmonary microemboli
Post thrombotic retinopathy	Pulmonary oil microembolism
Post thrombotic syndrome	Pulmonary renal syndrome
Post viral fatigue syndrome	Pulmonary sarcoidosis
Postictal headache	Pulmonary sepsis
Postictal paralysis	Pulmonary thrombosis
Postictal psychosis	Pulmonary tumour thrombotic microangiopathy
Postictal state	Pulmonary vasculitis
Postoperative respiratory distress	Pulmonary veno-occlusive disease
Postoperative respiratory failure	Pulmonary venous thrombosis
Postoperative thrombosis	Pyoderma gangrenosum
Postpartum thrombosis	Pyostomatitis vegetans
Postpartum venous thrombosis	Pyrexia
Postpericardiotomy syndrome;	Quarantine
Post-traumatic epilepsy	Radiation leukopenia
Postural orthostatic tachycardia syndrome	Radiculitis brachial
Precerebral artery thrombosis	Radiologically isolated syndrome
Pre-eclampsia	Rash
Preictal state	Rash erythematous
Premature labour	Rash pruritic
Premature menopause	Rasmussen encephalitis
Primary amyloidosis	Raynaud's phenomenon
Primary biliary cholangitis	Reactive capillary endothelial proliferation
Primary progressive multiple sclerosis	Relapsing multiple sclerosis
Procedural shock	Relapsing-remitting multiple sclerosis
Proctitis herpes	Renal amyloidosis
Proctitis ulcerative	Renal arteritis
Product availability issue	

Renal artery thrombosis	SARS-CoV-2 antibody test
Renal embolism;	SARS-CoV-2 antibody test negative
Renal failure	SARS-CoV-2 antibody test positive
Renal vascular thrombosis	SARS-CoV-2 carrier
Renal vasculitis	SARS-CoV-2 sepsis
Renal vein embolism	ARS-CoV-2 test
Renal vein thrombosis	SARS- CoV-2 test false negative
Respiratory arrest	SARS-CoV-2 test false positive
Respiratory disorder	SARS-CoV-2 test negative
Respiratory distress	SARS- CoV-2 test positive
Respiratory failure	SARS-CoV-2 viraemia
Respiratory paralysis	Satoyoshi syndrome
Respiratory syncytial virus bronchiolitis	Schizencephaly
Respiratory syncytial virus bronchitis	Scleritis
Retinal artery embolism	Sclerodactylia
Retinal artery occlusion	Scleroderma
Retinal artery thrombosis	Scleroderma associated digital ulcer
Retinal vascular thrombosis	Scleroderma renal crisis
Retinal vasculitis	Scleroderma-like reaction
Retinal vein occlusion	Secondary amyloidosis
Retinal vein thrombosis	Secondary cerebellar degeneration
Retinol binding protein decreased	Secondary progressive multiple sclerosis
Retinopathy	Segmented hyalinising vasculitis
Retrograde portal vein flow	Seizure
Retroperitoneal fibrosis	Seizure anoxic
Reversible airways obstruction	Seizure cluster
Reynold's syndrome	Seizure like phenomena
Rheumatic brain disease	Seizure prophylaxis
Rheumatic disorder	Sensation of foreign body
Rheumatoid arthritis;	Septic embolus
heumatoid factor increased	Septic pulmonary embolism
Rheumatoid factor positive	Severe acute respiratory syndrome
Rheumatoid factor quantitative increased	Severe myoclonic epilepsy of infancy shock
Rheumatoid lung	Shock symptom;
Rheumatoid neutrophilic dermatosis	Shrinking lung syndrome
Rheumatoid nodule	Shunt thrombosis
Rheumatoid nodule removal	Silent thyroiditis
Rheumatoid scleritis	Simple partial seizures
Rheumatoid vasculitis	Sjogren's syndrome
Saccadic eye movement	Skin swelling
APHO syndrome	SLE arthritis
Sarcoidosis	Smooth muscle antibody positive
SARS-CoV-1 test	Sneezing
SARS-CoV-1 test negative	Spinal artery embolism
SARS-CoV-1 test positive	Spinal artery thrombosis

Splenic artery thrombosis	Tachypnoea
Splenic embolism	Takayasu's arteritis
Splenic thrombosis	Temporal lobe epilepsy
Splenic vein thrombosis	Terminal ileitis
Spondylitis	Testicular autoimmunity
Spondyloarthropathy	Throat tightness
Spontaneous heparin-induced thrombocyto-	Thromboangiitis obliterans
penia syndrome	Thrombocytopenia
Status epilepticus	Thrombocytopenic purpura
Stevens-Johnson syndrome	Thrombophlebitis
Stiff leg syndrome	Thrombophlebitis migrans
Stiff person syndrome	Thrombophlebitis neonatal
Stillbirth	Thrombophlebitis septic
Still's disease	Thrombophlebitis superficial
Stoma site thrombosis	Thromboplastin antibody positive
Stoma site vasculitis	Thrombosis;Thrombosis corpora cavernosa
Stress cardiomyopathy	Thrombosis in device
Stridor	Thrombosis mesenteric vessel
Subacute cutaneous lupus erythematosu	Thrombotic cerebral infarction
Subacute endocarditis	Thrombotic microangiopathy
Subacute inflammatory demyelinating poly-	Thrombotic stroke
neuropathy	Thrombotic thrombocytopenic purpura
Subclavian artery embolism	Thyroid disorder
Subclavian artery thrombosis	Thyroid stimulating immunoglobulin in-
Subclavian vein thrombosis	creased
Sudden unexplained death in epilepsy	Thyroiditis
Superior sagittal sinus thrombosis	Tongue amyloidosis
Susac's syndrome	Tongue biting
Suspected COVID- 19	Tongue oedema
Swelling	Tonic clonic movement
Swelling face	Tonic convulsion
Swelling of eyelid	Tonic posturing
Swollen tongue	Topectomy
Sympathetic ophthalmia	Total bile acids increased
Systemic lupus erythematosus	Toxic epidermal necrolysis
Systemic lupus erythematosus disease activi-	Toxic leukoencephalopathy
ty index abnormal	Toxic oil syndrome
Systemic lupus erythematosus disease activi-	Tracheal obstruction
ty index decreased	Tracheal oedema
Systemic lupus erythematosus disease activi-	Tracheobronchitis
ty index increased	Tracheobronchitis mycoplasmal
Systemic lupus erythematosus rash	Tracheobronchitis viral
Systemic scleroderma	Transaminases abnormal
Systemic sclerosis pulmonary	Transaminases increased
Tachycardia	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

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^a.</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 ($\geq 2\%$) 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"> Number of cases: 413^a (0.98% of the total PM dataset); 84 serious and 329 non-serious; Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. <p>Pregnancy cases: 274 cases including:</p> <ul style="list-style-type: none"> 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. <p>Breast feeding baby cases: 133, of which:</p> <ul style="list-style-type: none"> 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). <p>Breast feeding mother cases (6):</p> <ul style="list-style-type: none"> 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia 1 non-serious case reported with very limited information and without associated AEs.

Table 6. Description of Missing Information

Topic	Description
Missing Information	<p>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)</p> <ul style="list-style-type: none"> 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). <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 <12 years of age</u></p> <ul style="list-style-type: none"> Number of cases: 34^d (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; Country of incidence: UK (29), US (3), Germany and Andorra (1 each); Cases Seriousness: Serious (24), Non-Serious (10); Gender: Females (25), Males (7), Unknown (2); Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). <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"> PT "Vaccination failure" is coded when ALL of the following criteria are met: <ul style="list-style-type: none"> The subject has received the series of two doses per the dosing regimen in local labeling. At least 7 days have elapsed since the second dose of vaccine has been administered. The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). PT "Drug ineffective" is coded when either of the following applies: <ul style="list-style-type: none"> 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". It is unknown: <ul style="list-style-type: none"> Whether the subject has received the series of two doses per the dosing regimen in local labeling; How many days have passed since the first dose (including unspecified number of days like "a few days", "some days", etc.); If 7 days have passed since the second dose; 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. <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"

Lack of efficacy cases

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

Drug ineffective cases (1649)

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

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

Table 6. Description of Missing Information

Topic	Description
Missing Information	<p>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)</p> <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><i>Vaccination failure cases (16)</i></p> <ul style="list-style-type: none"> • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: <ul style="list-style-type: none"> ○ Within 7 and 13 days: 8 subjects; ○ Within 15 and 29 days: 6 subjects. <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.