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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	Ammonia abnormal
2-Hydroxyglutaric aciduria	Ammonia increased
5'nucleotidase increased	Amniotic cavity infection
Acoustic neuritis	Amygdalohippocampectomy
Acquired C1 inhibitor deficiency	Amyloid arthropathy
Acquired epidermolysis bullosa	Amyloidosis
Acquired epileptic aphasia	Amyloidosis senile
Acute cutaneous lupus erythematosus	Anaphylactic reaction
Acute disseminated encephalomyelitis	Anaphylactic shock
Acute encephalitis with refractory, repetitive partial seizures	Anaphylactic transfusion reaction
Acute febrile neutrophilic dermatosis	Anaphylactoid reaction
Acute flaccid myelitis	Anaphylactoid shock
Acute haemorrhagic leukoencephalitis	Anaphylactoid syndrome of pregnancy
Acute haemorrhagic oedema of infancy	Angioedema
Acute kidney injury	Angiopathic neuropathy
Acute macular outer retinopathy	Ankylosing spondylitis
Acute motor axonal neuropathy	Anosmia
Acute motor-sensory axonal neuropathy	Antiacetylcholine receptor antibody positive
Acute myocardial infarction	Anti-actin antibody positive
Acute respiratory distress syndrome	Anti-aquaporin-4 antibody positive
Acute respiratory failure;Addison's disease	Anti-basal ganglia antibody positive
Administration site thrombosis	Anti-cyclic citrullinated peptide antibody positive
Administration site vasculitis	Anti-epithelial antibody positive
Adrenal thrombosis	Anti-erythrocyte antibody positive
Adverse event following immunisation	Anti-exosome complex antibody positive
Ageusia;Agranulocytosis	Anti-GAD antibody negative
Air embolism	Anti-GAD antibody positive
Alanine aminotransferase abnormal	Anti-ganglioside antibody positive
Alanine aminotransferase increased	Antigliadin antibody positive
Alcoholic seizure	Anti-glomerular basement membrane antibody positive
Allergic bronchopulmonary mycosis	Anti-glomerular basement membrane disease
Allergic oedema;Alloimmune hepatitis	Anti-glycyl-tRNA synthetase antibody positive
Alopecia areata	Anti-HLA antibody test positive
Alpers disease	Anti-IA2 antibody positive
Alveolar proteinosis	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	Bromosulphphalein 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	Disseminated neonatal herpes simplex
Cranial nerve disorder	Disseminated varicella
Cranial nerve palsies multiple	Disseminated varicella zoster vaccine virus infection
Cranial nerve paralysis	Disseminated varicella zoster virus infection
CREST syndrome	DNA antibody positive;Double cortex syndrome
Crohn's disease	Double stranded DNA antibody positive
Cryofibrinogenaemia	Dreamy state
Cryoglobulinaemia	Dressler's syndrome
CSF oligoclonal band present	Drop attacks
CSWS syndrome	Drug withdrawal convulsions
Cutaneous amyloidosis	Dyspnoea
Cutaneous lupus erythematosus	Early infantile epileptic encephalopathy with burst-suppression
Cutaneous sarcoidosis	Eclampsia
Cutaneous vasculitis	Eczema herpeticum
Cyanosis	Embolia cutis medicamentosa
Cyclic neutropenia	Embolic cerebellar infarction
Cystitis interstitial	Embolic cerebral infarction
Cytokine release syndrome	Embolic pneumonia
Cytokine storm	Embolic stroke
De novo purine synthesis inhibitors associated acute inflammatory syndrome	Embolism
Death neonatal	Embolism arterial
Deep vein thrombosis	Embolism venous
Deep vein thrombosis postoperative	Encephalitis
Deficiency of bile secretion	Encephalitis allergic
Deja vu	Encephalitis autoimmune
Demyelinating polyneuropathy	Encephalitis brain stem
Demyelination	Encephalitis haemorrhagic
Dermatitis	Encephalitis periaxialis diffusa
Dermatitis bullous	Encephalitis post immunisation
Dermatitis herpetiformis	Encephalomyelitis
Dermatomyositis	Encephalopathy
Device embolisation	Endocrine disorder
Device related thrombosis	Endocrine ophthalmopathy
Diabetes mellitus	Endotracheal intubation
Diabetic ketoacidosis	Enteritis
Diabetic mastopathy	Enteritis leukopenic
Dialysis amyloidosis	Enterobacter pneumonia
Dialysis membrane reaction	Enterocolitis
Diastolic hypotension	Enteropathic spondylitis
Diffuse vasculitis	Eosinopenia
Digital pitting scar	Eosinophilic fasciitis
Disseminated intravascular coagulation	Eosinophilic granulomatosis with polyangiitis
Disseminated intravascular coagulation in newborn	

Eosinophilic oesophagitis	Galactose elimination capacity test abnormal
Epidermolysis	Galactose elimination capacity test decreased
Epilepsy	Gamma-glutamyltransferase abnormal
Epilepsy surgery	Gamma-glutamyltransferase increased
Epilepsy with myoclonic-ataxic seizures	Gastritis herpes
Epileptic aura	Gastrointestinal amyloidosis
Epileptic psychosis	Gelastic seizure
Erythema	Generalised onset non-motor seizure
Erythema induratum	Generalised tonic-clonic seizure
Erythema multiforme	Genital herpes
Erythema nodosum	Genital herpes simplex
Evans syndrome	Genital herpes zoster
Exanthema subitum	Giant cell arteritis
Expanded disability status scale score decreased	Glomerulonephritis
Expanded disability status scale score increased	Glomerulonephritis membranoproliferative
Exposure to communicable disease	Glomerulonephritis membranous
Exposure to SARS-CoV-2	Glomerulonephritis rapidly progressive
Eye oedema	Glossopharyngeal nerve paralysis
Eye pruritus	Glucose transporter type 1 deficiency syndrome
Eye swelling	Glutamate dehydrogenase increased
Eyelid oedema	Glycocholic acid increased
Face oedema	GM2 gangliosidosis
Facial paralysis	Goodpasture's syndrome
Facial paresis	Graft thrombosis
Faciobrachial dystonic seizure	Granulocytopenia
Fat embolism	Granulocytopenia neonatal
Febrile convulsion	Granulomatosis with polyangiitis
Febrile infection-related epilepsy syndrome	Granulomatous dermatitis
Febrile neutropenia	Grey matter heterotopia
Felty's syndrome	Guanase increased
Femoral artery embolism	Guillain-Barre syndrome
Fibrillary glomerulonephritis	Haemolytic anaemia
Fibromyalgia	Haemophagocytic lymphohistiocytosis
Flushing	Haemorrhage
Foaming at mouth	Haemorrhagic ascites
Focal cortical resection	Haemorrhagic disorder
Focal dyscognitive seizures	Haemorrhagic pneumonia
Foetal distress syndrome	Haemorrhagic varicella syndrome
Foetal placental thrombosis	Haemorrhagic vasculitis
Foetor hepaticus	Hantavirus pulmonary infection
Foreign body embolism	Hashimoto's encephalopathy
Frontal lobe epilepsy	Hashitoxicosis
Fulminant type 1 diabetes mellitus	Hemimegalencephaly
	Henoch-Schonlein purpura

Henoch-Schonlein purpura nephritis	Herpes simplex meningoencephalitis
Hepaplastin abnormal	Herpes simplex meningomyelitis
Hepaplastin decreased	Herpes simplex necrotising retinopathy
Heparin-induced thrombocytopenia	Herpes simplex oesophagitis
Hepatic amyloidosis	Herpes simplex otitis externa
Hepatic artery embolism	Herpes simplex pharyngitis
Hepatic artery flow decreased	Herpes simplex pneumonia
Hepatic artery thrombosis	Herpes simplex reactivation
Hepatic enzyme abnormal	Herpes simplex sepsis
Hepatic enzyme decreased	Herpes simplex viraemia
Hepatic enzyme increased	Herpes simplex virus conjunctivitis neonatal
Hepatic fibrosis marker abnormal	Herpes simplex visceral
Hepatic fibrosis marker increased	Herpes virus infection
Hepatic function abnormal	Herpes zoster
Hepatic hydrothorax	Herpes zoster cutaneous disseminated
Hepatic hypertrophy	Herpes zoster infection neurological
Hepatic hypoperfusion	Herpes zoster meningitis
Hepatic lymphocytic infiltration	Herpes zoster meningoencephalitis
Hepatic mass	Herpes zoster meningomyelitis
Hepatic pain	Herpes zoster meningoradiculitis
Hepatic sequestration	Herpes zoster necrotising retinopathy
Hepatic vascular resistance increased	Herpes zoster oticus
Hepatic vascular thrombosis	Herpes zoster pharyngitis
Hepatic vein embolism	Herpes zoster reactivation
Hepatic vein thrombosis	Herpetic radiculopathy
Hepatic venous pressure gradient abnormal	Histone antibody positive
Hepatic venous pressure gradient increased	Hoigne's syndrome
Hepatitis;Hepatobiliary scan abnormal	Human herpesvirus 6 encephalitis
Hepatomegaly	Human herpesvirus 6 infection
Hepatosplenomegaly	Human herpesvirus 6 infection reactivation
Hereditary angioedema with C1 esterase inhibitor deficiency	Human herpesvirus 7 infection
Herpes dermatitis	Human herpesvirus 8 infection
Herpes gestationis	Hyperammonaemia
Herpes oesophagitis	Hyperbilirubinaemia
Herpes ophthalmic	Hypercholia
Herpes pharyngitis	Hypergammaglobulinaemia benign monoclonal
Herpes sepsis	Hyperglycaemic seizure
Herpes simplex	Hypersensitivity
Herpes simplex cervicitis	Hypersensitivity vasculitis
Herpes simplex colitis	Hyperthyroidism
Herpes simplex encephalitis	Hypertransaminasaemia
Herpes simplex gastritis	Hyperventilation
Herpes simplex hepatitis	Hypoalbuminaemia
Herpes simplex meningitis	Hypocalcaemic seizure

Hypogammaglobulinaemia	Implant site thrombosis
Hypoglossal nerve paralysis	Inclusion body myositis
Hypoglossal nerve paresis	Infantile genetic agranulocytosis
Hypoglycaemic seizure	Infantile spasms
Hyponatraemic seizure	Infected vasculitis
Hypotension	Infective thrombosis
Hypotensive crisis	Inflammation
Hypothenar hammer syndrome	Inflammatory bowel disease
Hypothyroidism	Infusion site thrombosis
Hypoxia	Infusion site vasculitis
Idiopathic CD4 lymphocytopenia	Injection site thrombosis
Idiopathic generalised epilepsy	Injection site urticaria
Idiopathic interstitial pneumonia	Injection site vasculitis
Idiopathic neutropenia	Instillation site thrombosis
Idiopathic pulmonary fibrosis	Insulin autoimmune syndrome
IgA nephropathy	Interstitial granulomatous dermatitis
IgM nephropathy	Interstitial lung disease
IIIrd nerve paralysis	Intracardiac mass
IIIrd nerve paresis	Intracardiac thrombus
Iliac artery embolism	Intracranial pressure increased
Immune thrombocytopenia	Intrapericardial thrombosis
Immune-mediated adverse reaction	Intrinsic factor antibody abnormal
Immune-mediated cholangitis	Intrinsic factor antibody positive
Immune-mediated cholestasis	IPEX syndrome
Immune-mediated cytopenia	Irregular breathing
Immune-mediated encephalitis	IRVAN syndrome
Immune-mediated encephalopathy	IVth nerve paralysis
Immune-mediated endocrinopathy	IVth nerve paresis
Immune-mediated enterocolitis	JC polyomavirus test positive
Immune-mediated gastritis	JC virus CSF test positive
Immune-mediated hepatic disorder	Jeavons syndrome
Immune-mediated hepatitis	Jugular vein embolism
Immune-mediated hyperthyroidism	Jugular vein thrombosis
Immune-mediated hypothyroidism	Juvenile idiopathic arthritis
Immune-mediated myocarditis	Juvenile myoclonic epilepsy
Immune-mediated myositis	Juvenile polymyositis
Immune-mediated nephritis	Juvenile psoriatic arthritis
Immune-mediated neuropathy	Juvenile spondyloarthritis
Immune-mediated pancreatitis	Kaposi sarcoma inflammatory cytokine syndrome
Immune-mediated pneumonitis	Kawasaki's disease
Immune-mediated renal disorder	Kayser-Fleischer ring
Immune-mediated thyroiditis	Keratoderma blenorrhagica
Immune-mediated uveitis	Ketosis-prone diabetes mellitus
Immunoglobulin G4 related disease	Kounis syndrome
Immunoglobulins abnormal	

Lafora's myoclonic epilepsy	Lupus endocarditis
Lambl's excrescences	Lupus enteritis
Laryngeal dyspnoea	Lupus hepatitis
Laryngeal oedema	Lupus myocarditis
Laryngeal rheumatoid arthritis	Lupus myositis
Laryngospasm	Lupus nephritis
Laryngotracheal oedema	Lupus pancreatitis
Latent autoimmune diabetes in adults	Lupus pleurisy
LE cells present	Lupus pneumonitis
Lemierre syndrome	Lupus vasculitis
Lennox-Gastaut syndrome	Lupus-like syndrome
Leucine aminopeptidase increased	Lymphocytic hypophysitis
Leukoencephalomyelitis	Lymphocytopenia neonatal
Leukoencephalopathy	Lymphopenia
Leukopenia	MAGIC syndrome
Leukopenia neonatal	Magnetic resonance imaging liver abnormality
Lewis-Sumner syndrome	Magnetic resonance proton density fat fraction measurement
Lhermitte's sign	Mahler sign
Lichen planopilaris	Manufacturing laboratory analytical testing issue
Lichen planus	Manufacturing materials issue
Lichen sclerosus	Manufacturing production issue
Limbic encephalitis	Marburg's variant multiple sclerosis
Linear IgA disease	Marchiafava-Bignami disease
Lip oedema; lip swelling	Marine Lenhart syndrome
Liver function test abnormal	Mastocytic enterocolitis
Liver function test decreased	Maternal exposure during pregnancy
Liver function test increased	Medical device site thrombosis
Liver induration	Medical device site vasculitis
Liver injury	MELAS syndrome
Liver iron concentration abnormal	Meningitis
Liver iron concentration increased	Meningitis aseptic
Liver opacity	Meningitis herpes
Liver palpable	Meningoencephalitis herpes simplex neonatal
Liver sarcoidosis	Meningoencephalitis herpetic
Liver scan abnormal	Meningomyelitis herpes
Liver tenderness	MERS-CoV test
Low birth weight baby	MERS-CoV test negative
Lower respiratory tract herpes infection	MERS-CoV test positive
Lower respiratory tract infection	Mesangioproliferative glomerulonephritis
Lower respiratory tract infection viral	Mesenteric artery embolism
Lung abscess	Mesenteric artery thrombosis
Lupoid hepatic cirrhosis	Mesenteric vein thrombosis
Lupus cystitis	
Lupus encephalitis	

Metapneumovirus infection	Myoclonic epilepsy
Metastatic cutaneous Crohn's disease	Myoclonic epilepsy and ragged-red fibres
Metastatic pulmonary embolism	Myokymia
Microangiopathy	Myositis
Microembolism	Narcolepsy
Microscopic polyangiitis	Nasal herpes
Middle East respiratory syndrome	Nasal obstruction
Migraine-triggered seizure	Necrotising herpetic retinopathy
Miliary pneumonia	Neonatal Crohn's disease
Miller Fisher syndrome	Neonatal epileptic seizure
Mitochondrial aspartate aminotransferase increased	Neonatal lupus erythematosus
Mixed connective tissue disease	Neonatal mucocutaneous herpes simplex
Model for end stage liver disease score abnormal	Neonatal pneumonia
Model for end stage liver disease score increased	Neonatal seizure
Molar ratio of total branched-chain amino acid to tyrosine	Nephritis
Molybdenum cofactor deficiency	Nephrogenic systemic fibrosis
Monocytopenia	Neuralgic amyotrophy
Mononeuritis	Neuritis
Mononeuropathy multiplex	Neuritis cranial
Morphea	Neuromyelitis optica pseudo relapse
Morvan syndrome	Neuromyelitis optica spectrum disorder
Mouth swelling	Neuromyotonia
Moyamoya disease	Neuronal neuropathy
Multifocal motor neuropathy	Neuropathy peripheral
Multiple organ dysfunction syndrome	Neuropathy, ataxia, retinitis pigmentosa syndrome
Multiple sclerosis	Neuropsychiatric lupus
Multiple sclerosis relapse	Neurosarcoidosis
Multiple sclerosis relapse prophylaxis	Neutropenia
Multiple subpial transection	Neutropenia neonatal
Multisystem inflammatory syndrome in children	Neutropenic colitis
Muscular sarcoidosis	Neutropenic infection
Myasthenia gravis	Neutropenic sepsis
Myasthenia gravis crisis	Nodular rash
Myasthenia gravis neonatal	Nodular vasculitis
Myasthenic syndrome	Noninfectious myelitis
Myelitis	Noninfective encephalitis
Myelitis transverse	Noninfective encephalomyelitis
Myocardial infarction	Noninfective oophoritis
Myocarditis	Obstetrical pulmonary embolism
Myocarditis post infection	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	Polyarthritis
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	Sclerodactyla
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 thrombocytopenia syndrome	Thromboangiitis obliterans
Status epilepticus	Thrombocytopenia
Stevens-Johnson syndrome	Thrombocytopenic purpura
Stiff leg syndrome	Thrombophlebitis
Stiff person syndrome	Thrombophlebitis migrans
Stillbirth	Thrombophlebitis neonatal
Still's disease	Thrombophlebitis septic
Stoma site thrombosis	Thrombophlebitis superficial
Stoma site vasculitis	Thromboplastin antibody positive
Stress cardiomyopathy	Thrombosis;Thrombosis corpora cavernosa
Stridor	Thrombosis in device
Subacute cutaneous lupus erythematosus	Thrombosis mesenteric vessel
Subacute endocarditis	Thrombotic cerebral infarction
Subacute inflammatory demyelinating polyneuropathy	Thrombotic microangiopathy
Subclavian artery embolism	Thrombotic stroke
Subclavian artery thrombosis	Thrombotic thrombocytopenic purpura
Subclavian vein thrombosis	Thyroid disorder
Sudden unexplained death in epilepsy	Thyroid stimulating immunoglobulin increased
Superior sagittal sinus thrombosis	Thyroiditis
Susac's syndrome	Tongue amyloidosis
Suspected COVID- 19	Tongue biting
Swelling	Tongue oedema
Swelling face	Tonic clonic movement
Swelling of eyelid	Tonic convulsion
Swollen tongue	Tonic posturing
Sympathetic ophthalmia	Topectomy
Systemic lupus erythematosus	Total bile acids increased
Systemic lupus erythematosus disease activity index abnormal	Toxic epidermal necrolysis
Systemic lupus erythematosus disease activity index decreased	Toxic leukoencephalopathy
Systemic lupus erythematosus disease activity index increased	Toxic oil syndrome
Systemic lupus erythematosus rash	Tracheal obstruction
Systemic scleroderma	Tracheal oedema
Systemic sclerosis pulmonary	Tracheobronchitis
Tachycardia	Tracheobronchitis mycoplasmal
	Tracheobronchitis viral
	Transaminases abnormal
	Transaminases increased
	Transfusion-related alloimmune neutropenia

Transient epileptic amnesia	Vascular stent thrombosis
Transverse sinus thrombosis	Vasculitic rash
Trigeminal nerve paresis	Vasculitic ulcer
Trigeminal neuralgia	Vasculitis
Trigeminal palsy	Vasculitis gastrointestinal
Truncus coeliacus thrombosis	Vasculitis necrotising
Tuberous sclerosis complex	Vena cava embolism
Tubulointerstitial nephritis and uveitis syndrome	Vena cava thrombosis
Tumefactive multiple sclerosis	Venous intravasation
Tumour embolism	Venous recanalisation
Tumour thrombosis	Venous thrombosis
Type 1 diabetes mellitus	Venous thrombosis in pregnancy
Type I hypersensitivity	Venous thrombosis limb
Type III immune complex mediated reaction	Venous thrombosis neonatal
Uhthoff's phenomenon	Vertebral artery thrombosis
Ulcerative keratitis	Vessel puncture site thrombosis
Ultrasound liver abnormal	Visceral venous thrombosis
Umbilical cord thrombosis	VIth nerve paralysis
Uncinate fits	VIth nerve paresis
Undifferentiated connective tissue disease	Vitiligo
Upper airway obstruction	Vocal cord paralysis
Urine bilirubin increased	Vocal cord paresis
Urobilinogen urine decreased	Vogt-Koyanagi-Harada disease
Urobilinogen urine increased	Warm type haemolytic anaemia
Urticaria	Wheezing
Urticaria papular	White nipple sign
Urticular vasculitis	XIth nerve paralysis
Uterine rupture	X-ray hepatobiliary abnormal
Uveitis	Young's syndrome
Vaccination site thrombosis	Zika virus associated Guillain Barre syndrome
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	

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;</p> <p>Cases Seriousness: 138;</p> <p>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).</p> <p>Gender: Females (73), Males (57), Unknown (8);</p> <p>Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5);</p> <p>Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8);</p> <p>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	<p>Number of cases: 413^a (0.98% of the total PM dataset); 84 serious and 329 non-serious;</p> <ul style="list-style-type: none"> 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 style="text-align: center;">Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)</p>
Use in Paediatric Individuals <12 Years of Age	<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 has 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>Vaccination failure cases (16)</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.