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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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FDA-CBER-2021-5683-0000054

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome
2-Hydroxyglutaric aciduria
5'nucleotidase increased
Acoustic neuritis
Acquired C1 inhibitor deficiency
Acquired epidermolysis bullosa
Acquired epileptic aphasia
Acute cutaneous lupus erythematosus
Acute disseminated encephalomyelitis
Acute encephalitis with refractory, repetitive partial seizures
Acute febrile neutrophilic dermatosis
Acute flaccid myelitis
Acute haemorrhagic leukoencephalitis
Acute haemorrhagic oedema of infancy
Acute kidney injury
Acute macular outer retinopathy
Acute motor axonal neuropathy
Acute motor-sensory axonal neuropathy
Acute myocardial infarction
Acute respiratory distress syndrome
Acute respiratory failure;Addison's disease
Administration site thrombosis
Administration site vasculitis
Adrenal thrombosis
Adverse event following immunisation
Ageusia;Agranulocytosis
Air embolism
Alanine aminotransferase abnormal
Alanine aminotransferase increased
Alcoholic seizure
Allergic bronchopulmonary mycosis
Allergic oedema;Alloimmune hepatitis
Alopecia areata
Alpers disease
Alveolar proteinosis
Ammonia abnormal
Ammonia increased
Amniotic cavity infection
Amygdalohippocampectomy
Amyloid arthropathy
Amyloidosis
Amyloidosis senile
Anaphylactic reaction
Anaphylactic shock
Anaphylactic transfusion reaction
Anaphylactoid reaction
Anaphylactoid shock
Anaphylactoid syndrome of pregnancy
Angioedema
Angiopathic neuropathy
Ankylosing spondylitis
Anosmia
Antiacetylcholine receptor antibody positive
Anti-actin antibody positive
Anti-aquaporin-4 antibody positive
Anti-basal ganglia antibody positive
Anti-cyclic citrullinated peptide antibody positive
Anti-epithelial antibody positive
Anti-erythrocyte antibody positive
Anti-exosome complex antibody positive
Anti- GAD antibody negative
Anti-GAD antibody positive
Anti-ganglioside antibody positive
Antigliadin antibody positive
Anti-glomerular basement membrane antibody positive
Anti-glomerular basement membrane disease
Anti-glycyl-tRNA synthetase antibody positive
Anti-HLA antibody test positive
Anti-IA2 antibody positive
Anti-insulin antibody increased
Anti-insulin antibody positive
Anti-insulin receptor antibody increased
Anti-insulin receptor antibody positive
Anti-interferon antibody negative
Anti-interferon antibody positive
Anti-islet cell antibody positive

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

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

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

COVID-19 treatment
Cranial nerve disorder
Cranial nerve palsies multiple
Cranial nerve paralysis
CREST syndrome
Crohn's disease
Cryofibrinogenaemia
Cryoglobulinaemia
CSF oligoclonal band present
CSWS syndrome
Cutaneous amyloidosis
Cutaneous lupus erythematosus
Cutaneous sarcoidosis
Cutaneous vasculitis
Cyanosis
Cyclic neutropenia
Cystitis interstitial
Cytokine release syndrome
Cytokine storm
De novo purine synthesis inhibitors associated acute inflammatory syndrome
Death neonatal
Deep vein thrombosis
Deep vein thrombosis postoperative
Deficiency of bile secretion
Deja vu
Demyelinating polyneuropathy
Demyelination
Dermatitis
Dermatitis bullous
Dermatitis herpetiformis
Dermatomyositis
Device embolisation
Device related thrombosis
Diabetes mellitus
Diabetic ketoacidosis
Diabetic mastopathy
Dialysis amyloidosis
Dialysis membrane reaction
Diastolic hypotension
Diffuse vasculitis
Digital pitting scar
Disseminated intravascular coagulation
Disseminated intravascular coagulation in newborn
Disseminated neonatal herpes simplex
Disseminated varicella
Disseminated varicella zoster vaccine virus infection
Disseminated varicella zoster virus infection
DNA antibody positive;Double cortex syndrome
Double stranded DNA antibody positive
Dreamy state
Dressler's syndrome
Drop attacks
Drug withdrawal convulsions
Dyspnoea
Early infantile epileptic encephalopathy with burst-suppression
Eclampsia
Eczema herpeticum
Embolia cutis medicamentosa
Embolic cerebellar infarction
Embolic cerebral infarction
Embolic pneumonia
Embolic stroke
Embolism
Embolism arterial
Embolism venous
Encephalitis
Encephalitis allergic
Encephalitis autoimmune
Encephalitis brain stem
Encephalitis haemorrhagic
Encephalitis periaxialis diffusa
Encephalitis post immunisation
Encephalomyelitis
Encephalopathy
Endocrine disorder
Endocrine ophthalmopathy
Endotracheal intubation
Enteritis
Enteritis leukopenic
Enterobacter pneumonia
Enterocolitis
Enteropathic spondylitis
Eosinopenia
Eosinophilic fasciitis
Eosinophilic granulomatosis with polyangiitis

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

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

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

Lafora's myoclonic epilepsy
Lambl's excrescences
Laryngeal dyspnoea
Laryngeal oedema
Laryngeal rheumatoid arthritis
Laryngospasm
Laryngotracheal oedema
Latent autoimmune diabetes in adults
LE cells present
Lemierre syndrome
Lennox-Gastaut syndrome
Leucine aminopeptidase increased
Leukoencephalomyelitis
Leukoencephalopathy
Leukopenia
Leukopenia neonatal
Lewis-Sumner syndrome
Lhermitte's sign
Lichen planopilaris
Lichen planus
Lichen sclerosus
Limbic encephalitis
Linear IgA disease
Lip oedema;
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 abnorma
Magnetic resonance proton density fat fraction measurement
Mahler sign
Manufacturing laboratory analytical testing issue
Manufacturing materials issue
Manufacturing production issue
Marburg's variant multiple sclerosis
Marchiafava-Bignami disease
Marine Lenhart syndrome
Mastocytic enterocolitis
Maternal exposure during pregnancy
Medical device site thrombosis
Medical device site vasculitis
MELAS syndrome
Meningitis
Meningitis aseptic
Meningitis herpes
Meningoencephalitis herpes simplex neonatal
Meningoencephalitis herpetic
Meningomyelitis herpes
MERS-CoV test
MERS-CoV test negative
MERS-CoV test positive
Mesangioproliferative glomerulonephritis
Mesenteric artery embolism
Mesenteric artery thrombosis
Mesenteric vein thrombosis

Metapneumovirus infection
Metastatic cutaneous Crohn's disease
Metastatic pulmonary embolism
Microangiopathy
Microembolism
Microscopic polyangiitis
Middle East respiratory syndrome
Migraine-triggered seizure
Miliary pneumonia
Miller Fisher syndrome
Mitochondrial aspartate aminotransferase increased
Mixed connective tissue disease
Model for end stage liver disease score abnormal
Model for end stage liver disease score increased
Molar ratio of total branched-chain amino acid to tyrosine
Molybdenum cofactor deficiency
Monocytopenia
Mononeuritis
Mononeuropathy multiplex
Morphoea
Morvan syndrome
Mouth swelling
Moyamoya disease
Multifocal motor neuropathy
Multiple organ dysfunction syndrome
Multiple sclerosis
Multiple sclerosis relapse
Multiple sclerosis relapse prophylaxis
Multiple subpial transection
Multisystem inflammatory syndrome in children
Muscular sarcoidosis
Myasthenia gravis
Myasthenia gravis crisis
Myasthenia gravis neonatal
Myasthenic syndrome
Myelitis
Myelitis transverse
Myocardial infarction
Myocarditis
Myocarditis post infection
Myoclonic epilepsy
Myoclonic epilepsy and ragged-red fibres
Myokymia
Myositis
Narcolepsy
Nasal herpes
Nasal obstruction
Necrotising herpetic retinopathy
Neonatal Crohn's disease
Neonatal epileptic seizure
Neonatal lupus erythematosus
Neonatal mucocutaneous herpes simplex
Neonatal pneumonia
Neonatal seizure
Nephritis
Nephrogenic systemic fibrosis
Neuralgic amyotrophy
Neuritis
Neuritis cranial
Neuromyelitis optica pseudo relapse
Neuromyelitis optica spectrum disorder
Neuromyotonia
Neuronal neuropathy
Neuropathy peripheral
Neuropathy, ataxia, retinitis pigmentosa syndrome
Neuropsychiatric lupus
Neurosarcoidosis
Neutropenia
Neutropenia neonatal
Neutropenic colitis
Neutropenic infection
Neutropenic sepsis
Nodular rash
Nodular vasculitis
Noninfectious myelitis
Noninfective encephalitis
Noninfective encephalomyelitis
Noninfective oophoritis
Obstetrical pulmonary embolism
Occupational exposure to communicable disease
Occupational exposure to SARS-CoV-2
Ocular hyperaemia
Ocular myasthenia

Ocular pemphigoid
Ocular sarcoidosis
Ocular vasculitis
Oculofacial paralysis
Oedema
Oedema blister
Oedema due to hepatic disease
Oedema mouth
Oesophageal achalasia
Ophthalmic artery thrombosis
Ophthalmic herpes simplex
Ophthalmic herpes zoster
Ophthalmic vein thrombosis
Optic neuritis
Optic neuropathy
Optic perineuritis
Oral herpes
Oral lichen planus
Oropharyngeal oedema
Oropharyngeal spasm
Oropharyngeal swelling
Osmotic demyelination syndrome
Ovarian vein thrombosis
Overlap syndrome
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
Paget-Schroetter syndrome
Palindromic rheumatism
Palisaded neutrophilic granulomatous dermatitis
Palmoplantar keratoderma
Palpable purpura
Pancreatitis
Panencephalitis
Papillophlebitis
Paracancerous pneumonia
Paradoxical embolism
Parainfluenzae viral laryngotracheobronchitis
Paraneoplastic dermatomyositis
Paraneoplastic pemphigus
Paraneoplastic thrombosis;
Paresis cranial nerve
Parietal cell antibody positive
Paroxysmal nocturnal haemoglobinuria
Partial seizures;
Partial seizures with secondary generalisation
Patient isolation
Pelvic venous thrombosis
Pemphigoid
Pemphigus;
Penile vein thrombosis
Pericarditis
Pericarditis lupus
Perihepatic discomfort
Periorbital oedema
Periorbital swelling
Peripheral artery thrombosis
Peripheral embolism
Peripheral ischaemia
Peripheral vein thrombus extension
Periportal oedema
Peritoneal fluid protein abnormal
Peritoneal fluid protein decreased
Peritoneal fluid protein increased
Peritonitis lupus
Pernicious anaemia
Petit mal epilepsy
Pharyngeal oedema
Pharyngeal swelling
Pityriasis lichenoides et varioliformis acuta
Placenta praevia
Pleuroparenchymal fibroelastosis
Pneumobilia
Pneumonia
Pneumonia adenoviral
Pneumonia cytomegaloviral
Pneumonia herpes viral
Pneumonia influenzal
Pneumonia measles
Pneumonia mycoplasmal
Pneumonia necrotising
Pneumonia parainfluenzae viral
Pneumonia respiratory syncytial viral
Pneumonia viral
POEMS syndrome
Polyarteritis nodosa
Polyarthritis
Polychondritis
Polyglandular autoimmune syndrome type I
Polyglandular autoimmune syndrome type II

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

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

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

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

Table 5. Important Potential Risk

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

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

Table 6. Description of Missing Information

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

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.

Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy:
	
	The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below:
	• PT "Vaccination failure" is coded when ALL of the following criteria are met:
	  ○ 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:
	  ○ 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:
	  ▪ 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.
	
	Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete.
	
	Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

Table 6. Description of Missing Information

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Missing Information</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)
<table>
<tr><td>1st dose (day 1-13)</td><td>From day 14 post 1st dose to day 6 post 2nd dose</td><td>Day 7 post 2nd dose</td></tr>
<tr><td>Code only the events describing the SARS-CoV-2 infection</td><td>Code “Drug ineffective”</td><td>Code “Vaccination failure”</td></tr>
<tr><td>Scenario Not considered LOE</td><td>Scenario considered LOE as “Drug ineffective”</td><td>Scenario considered LOE as “Vaccination failure”</td></tr>
</table>
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 </td></tr>
</table>

Table 6. Description of Missing Information

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

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

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