

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

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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; Anaphylactoid 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 mycoplasma;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

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tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;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;Embolitic cerebellar infarction;Embolitic cerebral infarction;Embolitic pneumonia;Embolitic 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

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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;Facio-brachial 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-Schönlein purpura;Henoch-Schönlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex 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; Hypertransaminaemia; Hyperventilation; Hypoalbuminaemia; Hypocalcaemic seizure; Hypogammaglobulinaemia; Hypoglossal nerve paralysis; Hypoglossal nerve paresis; Hypoglycaemic seizure; Hyponatraemic seizure; Hypotension; Hypotensive crisis; Hypothénar hammer syndrome; Hypothyroidism; Hypoxia; Idiopathic CD4 lymphocytopenia; Idiopathic generalised epilepsy; Idiopathic interstitial pneumonia; Idiopathic neutropenia; Idiopathic pulmonary fibrosis; IgA nephropathy; IgM nephropathy; IIIrd nerve paralysis; IIIrd nerve paresis; Iliac artery embolism; Immune thrombocytopenia; Immune-mediated adverse reaction; Immune-mediated cholangitis; Immune-mediated cholestasis; Immune-mediated cytopenia; Immune-mediated encephalitis; Immune-mediated encephalopathy; Immune-mediated endocrinopathy; Immune-mediated enterocolitis; Immune-mediated gastritis; Immune-mediated hepatic disorder; Immune-mediated hepatitis; Immune-mediated hyperthyroidism; Immune-mediated hypothyroidism; Immune-mediated myocarditis; Immune-mediated myositis; Immune-mediated nephritis; Immune-mediated neuropathy; Immune-mediated pancreatitis; Immune-mediated pneumonitis; Immune-mediated renal disorder; Immune-mediated thyroiditis; Immune-mediated uveitis; Immunoglobulin G4 related disease; Immunoglobulins abnormal; Implant site thrombosis; Inclusion body myositis; Infantile genetic agranulocytosis; Infantile spasms; Infected vasculitis; Infective thrombosis; Inflammation; Inflammatory bowel disease; Infusion site thrombosis; Infusion site vasculitis; Injection site thrombosis; Injection site urticaria; Injection site vasculitis; Instillation site thrombosis; Insulin autoimmune syndrome; Interstitial granulomatous dermatitis; Interstitial lung disease; Intracardiac mass; Intracardiac thrombus; Intracranial pressure increased; Intrapericardial thrombosis; Intrinsic factor antibody abnormal; Intrinsic factor antibody positive; IPEX syndrome; Irregular breathing; IRVAN syndrome; IVth nerve paralysis; IVth nerve paresis; JC polyomavirus test positive; JC virus CSF test positive; Jeavons syndrome; Jugular vein embolism; Jugular vein thrombosis; Juvenile idiopathic arthritis; Juvenile myoclonic epilepsy; Juvenile polymyositis; Juvenile psoriatic arthritis; Juvenile spondyloarthritis; Kaposi sarcoma inflammatory cytokine syndrome; Kawasaki's disease; Kayser-Fleischer ring; Keratoderma blennorrhagica; Ketosis-prone diabetes mellitus; Kounis syndrome; Lafora's myoclonic epilepsy; Lamb's excrescences; Laryngeal dyspnoea; Laryngeal oedema; Laryngeal rheumatoid arthritis; Laryngospasm; Laryngotracheal oedema; Latent autoimmune diabetes in adults; LE cells present; Lemièrre syndrome; Lennox-Gastaut syndrome; Leucine aminopeptidase increased; Leukoencephalomyelitis; Leukoencephalopathy; Leukopenia; Leukopenia neonatal; Lewis-Sumner syndrome; Lhermitte's sign; Lichen planopilaris; Lichen planus; Lichen sclerosus; Limbic encephalitis; Linear IgA disease; Lip oedema; Lip swelling; Liver function test abnormal; Liver function test decreased; Liver function test increased; Liver induration; Liver injury; Liver iron concentration abnormal; Liver iron concentration

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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 pleuritis; Lupus pneumonitis; Lupus vasculitis; Lupus-like syndrome; Lymphocytic hypophysitis; Lymphocytopenia neonatal; Lymphopenia; MAGIC syndrome; Magnetic resonance imaging liver abnormal; Magnetic resonance proton density fat fraction measurement; Mahler sign; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; Marburg's variant multiple sclerosis; Marchiafava-Bignami disease; Marine Lenhart syndrome; Mastocytic enterocolitis; Maternal exposure during pregnancy; Medical device site thrombosis; Medical device site vasculitis; MELAS syndrome; Meningitis; Meningitis aseptic; Meningitis herpes; Meningoencephalitis herpes simplex neonatal; Meningoencephalitis herpetic; Meningomyelitis herpes; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Mesangioproliferative glomerulonephritis; Mesenteric artery embolism; Mesenteric artery thrombosis; Mesenteric vein thrombosis; Metapneumovirus infection; Metastatic cutaneous Crohn's disease; Metastatic pulmonary embolism; Microangiopathy; Microembolism; Microscopic polyangiitis; Middle East respiratory syndrome; Migraine-triggered seizure; Miliary pneumonia; Miller Fisher syndrome; Mitochondrial aspartate aminotransferase increased; Mixed connective tissue disease; Model for end stage liver disease score abnormal; Model for end stage liver disease score increased; Molar ratio of total branched-chain amino acid to tyrosine; Molybdenum cofactor deficiency; Monocytopenia; Mononeuritis; Mononeuropathy multiplex; Morphoea; Morvan syndrome; Mouth swelling; Moyamoya disease; Multifocal motor neuropathy; Multiple organ dysfunction syndrome; Multiple sclerosis; Multiple sclerosis relapse; Multiple sclerosis relapse prophylaxis; Multiple subpalmar transverse; 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; Palmo-plantar keratoderma; Palpable purpura; Pancreatitis; Panencephalitis; Papillophlebitis; Paraneoplastic pneumonia; Paradoxical embolism; Parainfluenzae viral laryngotracheobronchitis; Paraneoplastic dermatomyositis; Paraneoplastic pemphigus; Paraneoplastic thrombosis; Paresis cranial nerve; Parietal cell antibody positive; Paroxysmal nocturnal haemoglobinuria; Partial seizures; Partial seizures with secondary generalisation; Patient isolation; Pelvic venous thrombosis; Pemphigoid; Pemphigus; Penile vein thrombosis; Pericarditis; Pericarditis lupus; Perihepatic discomfort; Periorbital oedema; Periorbital swelling; Peripheral artery thrombosis; Peripheral embolism; Peripheral ischaemia; Peripheral vein thrombus extension; Periportal oedema; Peritoneal fluid protein abnormal; Peritoneal fluid protein decreased; Peritoneal fluid protein increased; Peritonitis lupus; Pernicious anaemia; Petit mal epilepsy; Pharyngeal oedema; Pharyngeal swelling; Pityriasis lichenoides et varioliformis acuta; Placenta praevia; Pleuroparenchymal fibroelastosis; Pneumobilia; Pneumonia; Pneumonia adenoviral; Pneumonia cytomegaloviral; Pneumonia herpes viral; Pneumonia influenza; Pneumonia measles; Pneumonia mycoplasma; 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; Polynuropathy; Polynuropathy idiopathic progressive; Portal pyaemia; Portal vein embolism; Portal vein flow decreased; Portal vein pressure increased; Portal vein thrombosis; Portosplenomesenteric venous thrombosis; Post procedural hypotension; Post procedural pneumonia; Post procedural pulmonary embolism; Post stroke epilepsy; Post stroke seizure; Post thrombotic retinopathy; Post thrombotic syndrome; Post viral fatigue syndrome; Postictal headache; Postictal paralysis; Postictal psychosis; Postictal state; Postoperative respiratory distress; Postoperative respiratory failure; Postoperative thrombosis; Postpartum thrombosis; Postpartum venous thrombosis; Postpericardiotomy syndrome; Post-traumatic epilepsy; Postural orthostatic tachycardia syndrome; Precerebral artery thrombosis; Pre-eclampsia; Preictal state; Premature labour; Premature menopause; Primary amyloidosis; Primary biliary cholangitis; Primary progressive multiple sclerosis; Procedural shock; Proctitis herpes; Proctitis ulcerative; Product availability issue; Product distribution issue; Product supply issue; Progressive facial hemiatrophy; Progressive multifocal leukoencephalopathy; Progressive multiple sclerosis; Progressive relapsing multiple sclerosis; Prosthetic cardiac valve thrombosis; Pruritus; Pruritus allergic; Pseudovasculitis; Psoriasis; Psoriatic arthropathy; Pulmonary amyloidosis; Pulmonary artery thrombosis; Pulmonary embolism; Pulmonary fibrosis; Pulmonary haemorrhage; Pulmonary microemboli; Pulmonary oil microembolism; Pulmonary renal syndrome; Pulmonary sarcoidosis; Pulmonary sepsis; Pulmonary thrombosis; Pulmonary tumour thrombotic microangiopathy; Pulmonary vasculitis; Pulmonary veno-occlusive disease; Pulmonary venous thrombosis; Pyoderma gangrenosum; Pyostomatitis vegetans; Pyrexia; Quarantine; Radiation leukopenia; Radiculitis

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brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

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5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;Vlth nerve paralysis;Vlth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;Xlth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.