

9-page addendum titled LIST OF ADVERSE EVENTS OF SPECIAL INTEREST
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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;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

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coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical

benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile

output

decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated

increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot

chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase

increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated

increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure

decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe

syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem

thrombosis;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

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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;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

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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;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

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infection;Herpes zoster;Herpes zoster cutaneous
disseminated;Herpes zoster infection
neurological;Herpes zoster meningitis;Herpes zoster
meningoencephalitis;Herpes zoster
meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster
necrotising
retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes
zoster
reactivation;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;Hyperg
ammaglobulinaemia
benign monoclonal;Hyperglycaemic
seizure;Hypersensitivity;Hypersensitivity
vasculitis;Hyperthyroidism;Hypertransaminaemia;Hyperventilation;H
ypoalbuminaemia;H
ypocalcaemic 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;Iliac nerve
paralysis;Iliac 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;Lambert'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;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
pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like
syndrome;Lymphocytic
hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC
syndrome;Magnetic
resonance imaging liver abnormal;Magnetic resonance proton density
fat fraction
measurement;Mahler sign;Manufacturing laboratory analytical testing
issue;Manufacturing
materials issue;Manufacturing production issue;Marburg's variant
multiple
sclerosis;Marchiafava-Bignami disease;Marine Lenhart
syndrome;Mastocytic
enterocolitis;Maternal exposure during pregnancy;Medical device site
thrombosis;Medical
device site vasculitis;MELAS syndrome;Meningitis;Meningitis
aseptic;Meningitis
herpes;Meningoencephalitis herpes simplex
neonatal;Meningoencephalitis
herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test
negative;MERS-CoV test
positive;Mesangioproliferative glomerulonephritis;Mesenteric artery
embolism;Mesenteric
artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus
infection;Metastatic
cutaneous Crohn's disease;Metastatic pulmonary
embolism;Microangiopathy;Microembolism;Microscopic
polyangiitis;Middle East
respiratory syndrome;Migraine-triggered seizure;Miliary

pneumonia; Miller Fisher syndrome; Mitochondrial aspartate aminotransferase increased; Mixed connective tissue disease; Model for end stage liver disease score abnormal; Model for end stage liver disease score increased; Molar ratio of total branched-chain amino acid to tyrosine; Molybdenum cofactor deficiency; Monocytopenia; Mononeuritis; Mononeuropathy multiplex; Morphoea; Morvan syndrome; Mouth swelling; Moyamoya disease; Multifocal motor neuropathy; Multiple organ dysfunction syndrome; Multiple sclerosis; Multiple sclerosis relapse 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

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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; Polyarthritides; Polychondritis; Polyglandular autoimmune syndrome type I; Polyglandular autoimmune syndrome type II; Polyglandular autoimmune syndrome type III; Polyglandular disorder; Polymicrogyria; Polymyalgia rheumatica; Polymyositis; Polyneuropathy; Polyneuropathy idiopathic progressive; Portal pyaemia; Portal vein embolism; Portal vein flow decreased; Portal vein pressure increased; Portal vein thrombosis; Portosplenomesenteric venous thrombosis; Post procedural hypotension; Post procedural pneumonia; Post procedural pulmonary embolism; Post stroke

epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

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brachial;Radiologically isolated syndrome;Rash;Rash
erythematous;Rash pruritic;Rasmussen
encephalitis;Raynaud's phenomenon;Reactive capillary endothelial
proliferation;Relapsing
multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal
amyloidosis;Renal
arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal
vascular
thrombosis;Renal vasculitis;Renal vein embolism;Renal vein
thrombosis;Respiratory
arrest;Respiratory disorder;Respiratory distress;Respiratory
failure;Respiratory
paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial
virus
bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal
artery thrombosis;Retinal
vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal
vein thrombosis;Retinol
binding protein decreased;Retinopathy;Retrograde portal vein
flow;Retroperitoneal
fibrosis;Reversible airways obstruction;Reynold's
syndrome;Rheumatic brain
disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor
increased;Rheumatoid
factor positive;Rheumatoid factor quantitative increased;Rheumatoid
lung;Rheumatoid
neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule
removal;Rheumatoid
scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO
syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test
negative;SARS-CoV-1 test
positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test

negative;SARS-CoV-2
antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2
sepsis;SARS-CoV-2 test;SARS-
CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-
2 test negative;SARS-
CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi
syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Sclero
derma 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

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neonatal; Thrombophlebitis septic; Thrombophlebitis superficial; Thromboplastin antibody positive; Thrombosis; Thrombosis corpora cavernosa; Thrombosis in device; Thrombosis mesenteric vessel; Thrombotic cerebral infarction; Thrombotic microangiopathy; Thrombotic stroke; Thrombotic thrombocytopenic purpura; Thyroid disorder; Thyroid stimulating immunoglobulin increased; Thyroiditis; Tongue amyloidosis; Tongue biting; Tongue oedema; Tonic clonic movements; Tonic convulsion; Tonic posturing; Topectomy; Total bile acids increased; Toxic epidermal necrolysis; Toxic leukoencephalopathy; Toxic oil

syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type 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.