

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	Anaemia	5	0
		Marrow depression and hypoplastic anaemias	Aplasia pure red cell	1	0
			Aplastic anaemia	1	0
			Bone marrow failure	1	0
			Cytopenia	2	0
			Pancytopenia	1	0
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Increased tendency to bruise	2	0
		Coagulopathies	Antiphospholipid syndrome	1	0
			Coagulopathy	1	0
			Disseminated intravascular coagulation	1	0
	Haematological disorders NEC	Haematological disorders	Blood disorder	1	0
			Placental transfusion syndrome	1	0
	Haemolyses and related conditions	Anaemias haemolytic immune	Autoimmune haemolytic anaemia	1	0
		Anaemias haemolytic mechanical factor	Atypical haemolytic uraemic syndrome	1	0
			Haemolytic uraemic syndrome	2	0
		Haemolyses NEC	Haemolysis	1	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	71	0
			Thrombocytopenia	46	0
			Thrombocytopenic purpura	7	0
			Thrombotic thrombocytopenic purpura	8	0
	Red blood cell disorders	Polycythaemia (excl rubra vera)	Polycythaemia	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenitis	4	0
			Lymphadenopathy	232	0
			Lymphoid tissue hyperplasia	1	0
		Spleen disorders	Splenomegaly	3	0
	White blood cell disorders	Eosinophilic disorders	Eosinophilia	1	0
		Leukocytoses NEC	Leukocytosis	1	0

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			Monocytosis	2	0
			T-cell lymphocytosis	1	0
		Leukopenias NEC	Leukopenia	2	0
			Lymphopenia	4	0
		Neutropenias	Neutropenia	3	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Arrhythmia	1	0
			Bradycardia	17	0
			Extrasystoles	1	0
			Tachycardia	16	0
		Supraventricular arrhythmias	Atrial fibrillation	1	0
			Atrial tachycardia	1	0
			Sinus tachycardia	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	2	1
			Cardio-respiratory arrest	2	1
			Ventricular fibrillation	1	0
			Ventricular tachycardia	2	0
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiac disorder	2	0
			Cardiovascular disorder	1	0
		Cardiac signs and symptoms NEC	Palpitations	11	0
	Cardiac valve disorders	Pulmonary valvular disorders	Pulmonary valve stenosis	2	0
	Endocardial disorders	Endocarditis NEC	Endocarditis noninfective	1	1
	Heart failures	Heart failures NEC	Cardiac failure	2	1
			Cardiopulmonary failure	2	0
	Myocardial disorders	Noninfectious myocarditis	Myocarditis	5	2
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	2	0
		Pericardial disorders NEC	Pericardial effusion	2	0
Congenital, familial and genetic disorders	Blood and lymphatic system disorders congenital	Lymphatic system disorders congenital	Lymphatic malformation	1	1

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	Cardiac and vascular disorders congenital	Cardiac septal defects congenital	Atrioventricular septal defect	2	0
		Great vessel disorders congenital	Double outlet right ventricle	2	0
		Persistent foetal circulation disorders	Patent ductus arteriosus	1	0
	Chromosomal abnormalities, gene alterations and gene variants	Autosomal chromosomal abnormalities	Trisomy 21	2	0
		Gene mutations and other alterations NEC	Gene mutation	1	0
			Mutagenic effect	2	0
	Congenital and hereditary disorders NEC	Congenital disorders NEC	Congenital anomaly	2	0
			Congenital cyst	1	0
			VACTERL syndrome	2	0
	Ear and labyrinthine disorders congenital	External ear disorders congenital	Anomaly of external ear congenital	1	0
	Eye disorders congenital	Eyelid disorders congenital	Eyelid ptosis congenital	2	0
		Lens disorders congenital	Cataract congenital	1	0
		Ocular disorders congenital NEC	Congenital eye disorder	1	0
	Gastrointestinal tract disorders congenital	Anorectal disorders congenital	Preternatural anus	2	0
		Gastric disorders congenital	Pyloric stenosis	1	0
		Gastrointestinal tract disorders congenital NEC	Congenital umbilical hernia	1	0
		Oral cavity disorders congenital NEC	Tethered oral tissue	2	0
	Immune system disorders congenital	Immune system abnormalities congenital	Combined immunodeficiency	1	0
			Primary immunodeficiency syndrome	3	0
	Metabolic and nutritional disorders congenital	Inborn errors of amino acid metabolism	Phenylketonuria	1	0
	Musculoskeletal and connective tissue disorders congenital	Connective tissue disorders congenital	Hypermobility syndrome	1	0
		Musculoskeletal and connective tissue disorders of limbs congenital	Congenital foot malformation	1	0
			Developmental hip dysplasia	3	0
			Limb hypoplasia congenital	2	0

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			Limb reduction defect	2	0
			Talipes	3	0
		Musculoskeletal and connective tissue disorders of skull congenital	Plagiocephaly	1	0
		Musculoskeletal and connective tissue disorders of spine congenital	Congenital musculoskeletal disorder of spine	2	0
	Neurological disorders congenital	Cerebellar disorders congenital	Hereditary ataxia	1	0
		Cerebral disorders congenital	Congenital hydrocephalus	1	0
	Renal and urinary tract disorders congenital	Bladder disorders congenital	Congenital vesicoureteric reflux	1	0
		Renal disorders congenital	Congenital cystic kidney disease	2	0
	Reproductive tract and breast disorders congenital	Male reproductive tract disorders congenital	Cryptorchism	1	0
			Hydrocele	2	0
			Hypospadias	2	0
	Respiratory disorders congenital	Laryngeal and tracheal disorders congenital	Laryngomalacia	1	0
		Pulmonary and bronchial disorders congenital	Congenital pneumonia	1	0
			Pulmonary aplasia	2	0
			Pulmonary hypoplasia	2	0
	Skin and subcutaneous tissue disorders congenital	Skin and subcutaneous tissue disorders congenital NEC	Congenital naevus	1	0
			Congenital skin dimples	2	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear congestion	2	0
			Ear discomfort	3	0
			Ear pain	29	0
			Ear swelling	5	0
			Otorrhoea	4	0
			Ototoxicity	1	0
	External ear disorders (excl congenital)	External ear disorders NEC	Auricular swelling	1	0
			Excessive cerumen production	1	0
	Hearing disorders	Hearing losses	Deafness	14	0
			Deafness bilateral	1	0

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			Deafness neurosensory	21	0
			Deafness transitory	2	0
			Deafness unilateral	4	0
			Hypoacusis	12	0
			Sudden hearing loss	1	0
		Hyperacusia	Hyperacusis	2	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Inner ear disorder	1	0
			Meniere's disease	1	0
			Vestibular disorder	1	0
		Inner ear signs and symptoms	Tinnitus	6	0
			Vertigo	7	0
	Middle ear disorders (excl congenital)	Eustachian tube disorders	Eustachian tube dysfunction	1	0
		Tympanic membrane disorders (excl infections)	Tympanic membrane disorder	2	0
			Tympanic membrane perforation	1	0
Endocrine disorders	Adrenal gland disorders	Adrenal cortical hyperfunctions	Cushingoid	1	0
		Adrenal gland disorders NEC	Adrenal disorder	1	0
	Endocrine disorders of gonadal function	Endocrine abnormalities of puberty	Precocious puberty	1	0
	Thyroid gland disorders	Acute and chronic thyroiditis	Autoimmune thyroiditis	1	0
		Thyroid disorders NEC	Goitre	1	0
		Thyroid hyperfunction disorders	Hyperthyroidism	1	0
		Thyroid hypofunction disorders	Hypothyroidism	1	0
Eye disorders	Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	2	0
		Corneal structural change, deposit and degeneration	Xerophthalmia	1	0
		Lens structural change, deposit and degeneration (excl cataracts)	Aphakia	1	0
		Lid, lash and lacrimal structural disorders	Dacryostenosis acquired	1	0
	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	12	0

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		Ocular disorders NEC	Eye disorder	2	0
			Eye pain	22	0
			Eye swelling	31	0
			Ocular discomfort	1	0
			Periorbital oedema	16	0
			Periorbital swelling	3	0
	Glaucoma and ocular hypertension	Glaucomas (excl congenital)	Glaucoma	1	0
	Ocular haemorrhages and vascular disorders NEC	Ocular bleeding and vascular disorders NEC	Eye haemorrhage	1	0
	Ocular infections, irritations and inflammations	Conjunctival infections, irritations and inflammations	Conjunctivitis allergic	1	0
		Iris and uveal tract infections, irritations and inflammations	Iridocyclitis	3	0
		Lid, lash and lacrimal infections, irritations and inflammations	Blepharitis	2	0
			Erythema of eyelid	3	0
			Eyelid oedema	4	0
			Swelling of eyelid	9	0
		Ocular infections, inflammations and associated manifestations	Eye discharge	11	0
			Eye inflammation	2	0
			Eye irritation	2	0
			Eye pruritus	7	0
			Ocular hyperaemia	20	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Blepharospasm	1	0
			Excessive eye blinking	2	0
		Ocular nerve and muscle disorders	Extraocular muscle disorder	1	0
			Eye movement disorder	21	0
			Ophthalmoplegia	1	0
			Strabismus	9	0
		Pupil disorders	Anisocoria	1	0
			Mydriasis	2	0

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	Ocular sensory symptoms NEC	Ocular sensation disorders	Pupil fixed	3	0
			Asthenopia	1	0
			Photophobia	25	0
	Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit and degeneration	Vitreous floaters	1	0
		Orbital structural change, deposit and degeneration	Lid sulcus deepened	1	0
	Vision disorders	Refractive and accommodative disorders	Altered visual depth perception	1	0
			Hypermetropia	1	0
		Visual disorders NEC	Diplopia	3	0
			Vision blurred	6	0
		Visual field disorders	Visual field defect	1	0
		Visual impairment and blindness (excl colour blindness)	Blindness	2	0
			Blindness cortical	1	0
			Blindness transient	1	0
			Cortical visual impairment	1	0
			Visual impairment	15	0
Gastrointestinal disorders	Abdominal hernias and other abdominal wall conditions	Abdominal hernias NEC	Abdominal hernia	1	0
		Diaphragmatic hernias	Hiatus hernia	1	0
		Umbilical hernias	Umbilical hernia	2	0
	Anal and rectal conditions NEC	Anal and rectal signs and symptoms	Anal inflammation	1	0
	Dental and gingival conditions	Dental disorders NEC	Tooth disorder	2	0
		Gingival disorders, signs and symptoms NEC	Gingival pain	3	0
			Gingival swelling	2	0
		Gingival haemorrhages	Gingival bleeding	4	0
	Exocrine pancreas conditions	Acute and chronic pancreatitis	Pancreatitis acute	1	0
			Pancreatitis haemorrhagic	1	0
			Pancreatitis necrotising	1	0

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	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Functional gastrointestinal disorder	2	0
			Gastrointestinal disorder	7	0
	Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Gastric haemorrhage	1	0
			Oesophageal haemorrhage	1	0
		Intestinal haemorrhages	Rectal haemorrhage	3	0
		Non-site specific gastrointestinal haemorrhages	Gastrointestinal haemorrhage	1	0
			Haematemesis	2	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis	4	0
			Colitis ulcerative	1	0
			Crohn's disease	5	0
			Inflammatory bowel disease	5	0
		Gastritis (excl infective)	Gastritis	1	0
		Gastrointestinal inflammatory disorders NEC	Enteritis	1	0
		Oesophagitis (excl infective)	Oesophagitis	2	0
		Rectal inflammations NEC	Proctitis	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	287	0
			Diarrhoea haemorrhagic	2	0
			Infantile diarrhoea	1	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	27	0
			Gastrooesophageal reflux disease	5	0
		Gastrointestinal dyskinetic disorders	Change of bowel habit	3	0
			Gastrointestinal motility disorder	2	0
		Gastrointestinal spastic and hypermotility disorders	Defaecation urgency	1	0
			Frequent bowel movements	2	0
			Irritable bowel syndrome	1	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	3	0
			Eructation	1	0

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		Faecal abnormalities NEC	Abnormal faeces	4	0
			Faecaloma	3	0
			Faeces discoloured	11	0
			Faeces pale	1	0
			Faeces soft	1	0
			Mucous stools	2	0
		Flatulence, bloating and distension	Abdominal distension	10	0
			Flatulence	6	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	51	0
			Abdominal pain lower	3	0
			Abdominal pain upper	37	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	6	0
			Anal incontinence	4	0
			Dysphagia	5	0
			Odynophagia	1	0
		Nausea and vomiting symptoms	Infantile vomiting	3	0
			Nausea	94	0
			Regurgitation	1	0
			Retching	3	0
			Vomiting	465	0
			Vomiting projectile	19	0
	Gastrointestinal stenosis and obstruction	Gastrointestinal stenosis and obstruction NEC	Intestinal obstruction	1	0
			Intussusception	1	0
	Gastrointestinal vascular conditions	Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	Gastrointestinal necrosis	1	0
	Malabsorption conditions	Malabsorption syndromes	Coeliac disease	1	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Chapped lips	3	0
			Lip blister	1	0
			Oral disorder	2	0

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			Oral papule	1	0
		Oral soft tissue haemorrhages	Lip haemorrhage	1	0
			Mouth haemorrhage	2	0
		Oral soft tissue signs and symptoms	Hypoaesthesia oral	4	0
			Oral mucosal blistering	7	0
			Oral mucosal eruption	4	0
			Oral pain	7	0
			Paraesthesia oral	12	0
		Oral soft tissue swelling and oedema	Lip swelling	27	0
			Mouth swelling	6	0
		Stomatitis and ulceration	Aphthous ulcer	3	0
			Lip ulceration	2	0
			Mouth ulceration	21	0
			Stomatitis	7	0
	Peritoneal and retroperitoneal conditions	Peritoneal and retroperitoneal disorders	Ascites	1	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	1	0
			Salivary hypersecretion	3	0
		Salivary gland disorders NEC	Salivary gland mass	2	0
			Salivary gland pain	1	0
		Salivary gland enlargements	Parotid gland enlargement	70	0
			Salivary gland enlargement	12	0
			Submaxillary gland enlargement	1	0
	Tongue conditions	Tongue disorders	Tongue disorder	2	0
			Tongue geographic	1	0
			Tongue ulceration	5	0
		Tongue signs and symptoms	Glossodynia	2	0
			Strawberry tongue	1	0
			Swollen tongue	7	0

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			Tongue coated	3	0
			Tongue eruption	3	0
			Tongue erythema	1	0
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site erythema	1	0
			Administration site rash	1	0
			Administration site urticaria	2	0
		Application site reactions	Application site erythema	1	0
			Application site rash	1	0
		Infusion site reactions	Infusion site erythema	1	0
		Injection site reactions	Injection site abscess sterile	2	0
			Injection site bruising	10	0
			Injection site cyst	1	0
			Injection site discolouration	4	0
			Injection site discomfort	2	0
			Injection site eczema	1	0
			Injection site erythema	76	0
			Injection site indentation	1	0
			Injection site induration	8	0
			Injection site inflammation	55	0
			Injection site irritation	2	0
			Injection site mass	20	0
			Injection site oedema	2	0
			Injection site pain	47	0
			Injection site pruritus	13	0
			Injection site rash	27	0
			Injection site reaction	201	0
			Injection site swelling	64	0
			Injection site urticaria	1	0

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			Injection site vesicles	7	0
			Injection site warmth	10	0
		Instillation site reactions	Instillation site warmth	1	0
		Vaccination site reactions	Extensive swelling of vaccinated limb	4	0
			Vaccination site bruising	10	0
			Vaccination site discomfort	4	0
			Vaccination site erythema	101	0
			Vaccination site granuloma	1	0
			Vaccination site haematoma	1	0
			Vaccination site hypertrichosis	1	0
			Vaccination site induration	13	0
			Vaccination site inflammation	14	0
			Vaccination site joint erythema	2	0
			Vaccination site mass	27	0
			Vaccination site movement impairment	3	0
			Vaccination site nodule	1	0
			Vaccination site pain	45	0
			Vaccination site paraesthesia	1	0
			Vaccination site pruritus	10	0
			Vaccination site rash	36	0
			Vaccination site reaction	7	0
			Vaccination site swelling	88	0
			Vaccination site urticaria	2	0
			Vaccination site vesicles	3	0
			Vaccination site warmth	36	0
	Body temperature conditions	Febrile disorders	Pyrexia	1,785	0
	Fatal outcomes	Death and sudden death	Death	8	8

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			Sudden death	2	2
			Sudden infant death syndrome	4	4
	General system disorders NEC	Adverse effect absent	No adverse event	3	0
		Asthenic conditions	Asthenia	39	0
			Chronic fatigue syndrome	6	0
			Decreased activity	1	0
			Fatigue	138	0
			Malaise	332	0
		Feelings and sensations NEC	Chills	52	0
			Feeling abnormal	30	0
			Feeling cold	4	0
			Feeling drunk	1	0
			Feeling hot	56	0
			Feeling jittery	1	0
			Feeling of body temperature change	6	0
			Hangover	1	0
			Sensation of foreign body	1	0
			Thirst	4	0
			Thirst decreased	4	0
		Gait disturbances	Gait disturbance	40	0
			Gait inability	27	0
			Loss of control of legs	1	0
		General signs and symptoms NEC	Condition aggravated	5	0
			Crepitations	1	0
			Crying	115	0
			Developmental delay	30	0
			Developmental regression	8	0
			Energy increased	1	0

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			Foaming at mouth	1	0
			General physical health deterioration	1	0
			Glassy eyes	1	0
			High-pitched crying	9	0
			Ill-defined disorder	1	0
			Illness	50	0
			Induration	6	0
			Influenza like illness	38	0
			Irritability postvaccinal	2	0
			Local reaction	79	0
			Moaning	3	0
			Multiple organ dysfunction syndrome	1	1
			Peripheral swelling	191	0
			Screaming	74	0
			Secretion discharge	2	0
			Swelling	113	0
			Swelling face	70	0
		Inflammations	Granuloma	1	0
			Inflammation	35	0
			Polyserositis	1	0
			Systemic inflammatory response syndrome	1	0
		Mucosal findings abnormal	Mucosal disorder	1	0
			Mucosal haemorrhage	1	0
		Oedema NEC	Face oedema	19	0
			Generalised oedema	1	0
			Gravitational oedema	1	0
			Oedema	15	0

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			Oedema peripheral	23	0
		Pain and discomfort NEC	Chest discomfort	11	0
			Chest pain	16	0
			Discomfort	27	0
			Facial pain	3	0
			Non-cardiac chest pain	2	0
			Pain	120	0
			Tenderness	22	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	2	0
			Potentiating drug interaction	1	0
		Therapeutic and nontherapeutic responses	Adverse drug reaction	13	0
			Adverse event	2	0
			Adverse reaction	1	0
			Drug ineffective	21	0
			Post vaccination challenge strain shedding	1	0
			Therapy non-responder	23	0
			Vaccination failure	196	0
		Withdrawal and rebound effects	Withdrawal syndrome	1	0
	Tissue disorders NEC	Mass conditions NEC	Cyst	1	0
			Mass	6	0
			Nodule	2	0
Hepatobiliary disorders	Gallbladder disorders	Cholecystitis and cholelithiasis	Cholecystitis	1	0
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	5	0
		Hepatic enzymes and function abnormalities	Hepatic function abnormal	3	0
			Hypertransaminaemia	1	0
		Hepatic failure and associated disorders	Hepatic failure	1	0
		Hepatobiliary signs and symptoms	Hepatomegaly	1	0

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Immune system disorders		Hepatocellular damage and hepatitis NEC	Hepatosplenomegaly	2	0
			Hepatitis	3	0
			Hepatitis acute	1	0
			Reye's syndrome	1	1
	Allergic conditions	Allergic conditions NEC	Allergic oedema	1	0
			Allergy to metals	2	0
			Hypersensitivity	73	0
			Multiple allergies	1	0
			Serum sickness-like reaction	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergic reaction to excipient	1	0
			Allergy to vaccine	4	0
			Drug hypersensitivity	1	0
			Food allergy	3	0
			Milk allergy	2	0
			Reaction to excipient	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	102	1
			Anaphylactic shock	6	0
			Anaphylactoid reaction	11	0
		Atopic disorders	Atopy	1	0
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder	3	0
	Immune disorders NEC	Immune and associated conditions NEC	Bacille Calmette-Guerin scar reactivation	1	0
			Decreased immune responsiveness	1	0
			Haemophagocytic lymphohistiocytosis	6	3
			Immune system disorder	3	0
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Immunodeficiency	3	0
		Primary immunodeficiency syndromes	Selective IgG subclass deficiency	1	0

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Infections and infestations	Ancillary infectious topics	Infectious transmissions	Infection transmission via personal contact	1	0
			Infection via vaccinee	2	0
			Transmission of an infectious agent via product	1	0
		Inflammatory disorders following infection	Subacute sclerosing panencephalitis	2	0
	Bacterial infectious disorders	Bacterial infections NEC	Administration site cellulitis	1	0
			Cellulitis	96	0
			Citrobacter sepsis	1	0
			Gastrointestinal bacterial overgrowth	1	0
			Injection site cellulitis	17	0
			Meningitis bacterial	4	0
			Skin bacterial infection	2	0
			Vaccination site cellulitis	15	0
		Bordetella infections	Pertussis	1	0
		Borrelial infections	Lyme disease	1	0
			Relapsing fever	3	0
		Haemophilus infections	Haemophilus sepsis	1	0
		Neisseria infections	Meningitis meningococcal	3	0
			Meningococcal sepsis	3	1
		Staphylococcal infections	Staphylococcal abscess	1	0
		Streptococcal infections	Pneumonia pneumococcal	1	0
			Scarlet fever	1	0
			Streptococcal infection	1	0
	Fungal infectious disorders	Candida infections	Candida infection	1	0
			Oral candidiasis	5	0
			Vulvovaginal candidiasis	1	0
		Fungal infections NEC	Fungal infection	1	0

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			Fungal skin infection	1	0
		Pneumocystis infections	Pneumocystis jirovecii pneumonia	1	0
	Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Diarrhoea infectious	2	0
			Gastroenteritis	7	0
			Large intestine infection	1	1
		Bone and joint infections	Intervertebral discitis	3	0
		Cardiac infections	Pericarditis infective	1	0
		Central nervous system and spinal infections	Encephalitis	46	3
			Encephalitis brain stem	1	0
			Encephalomyelitis	1	0
			Meningitis	51	0
			Meningitis aseptic	8	0
			Myelitis	2	0
			Panencephalitis	1	1
		Dental and oral soft tissue infections	Gingivitis	1	0
			Parotitis	872	0
			Sialoadenitis	2	0
		Ear infections	Ear infection	22	0
			Labyrinthitis	2	0
			Mastoiditis	1	0
			Otitis media	30	0
			Otitis media acute	3	0
			Otitis media chronic	4	0
		Eye and eyelid infections	Conjunctivitis	69	0
			Eye infection	5	0
			Retinitis	1	0
		Infections NEC	Abscess	6	0
			Abscess limb	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Infection	7	0
			Infection susceptibility increased	1	0
			Injection site abscess	5	0
			Injection site infection	2	0
			Localised infection	2	0
			Respiratory tract infection	1	0
			Toxic shock syndrome	1	0
			Vaccination site infection	9	0
			Vestibulitis	1	0
		Lower respiratory tract and lung infections	Atypical pneumonia	1	0
			Bronchitis	5	0
			Lower respiratory tract infection	17	0
			Pneumonia	15	1
		Male reproductive tract infections	Epididymitis	1	0
			Orchitis	28	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	6	1
			Sepsis neonatal	1	0
			Septic shock	2	0
			Urosepsis	1	1
			Viraemia	1	0
		Skin structures and soft tissue infections	Dermatitis infected	1	0
			Eczema infected	3	0
			Pustule	2	0
			Pyoderma	1	0
			Rash pustular	2	0
			Skin infection	4	0
			Subcutaneous abscess	1	0
			Vaccination site pustule	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Upper respiratory tract infections	Croup infectious	7	0
			Epiglottitis	2	0
			Laryngitis	2	0
			Nasopharyngitis	38	0
			Pharyngitis	20	0
			Rhinitis	30	0
			Sinusitis	1	0
			Tonsillitis	21	0
			Upper respiratory tract infection	21	0
		Urinary tract infections	Urinary tract infection	6	0
		Vascular infections	Haematoma infection	1	0
	Mycobacterial infectious disorders	Tuberculous infections	Erythema induratum	8	0
			Meningitis tuberculous	1	0
			Tuberculosis	1	0
	Viral infectious disorders	Adenoviral infections	Adenovirus infection	2	0
			COVID-19	2	0
			Cytomegalovirus infection	3	0
		Epstein-Barr viral infections	Epstein-Barr viraemia	1	0
			Epstein-Barr virus infection	5	0
			Epstein-Barr virus infection reactivation	1	0
			Infectious mononucleosis	1	0
		Herpes viral infections	Herpes simplex	2	0
			Herpes zoster	6	0
			Human herpesvirus 6 infection	4	0
			Human herpesvirus 6 infection reactivation	1	0
			Human herpesvirus 7 infection	1	0
			Oral herpes	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Varicella	9	0
			Varicella zoster virus infection	1	0
		Influenza viral infections	H1N1 influenza	1	0
			Influenza	7	0
		Molluscum contagiosum viral infections	Molluscum contagiosum	2	0
		Mumps viral infections	Encephalitis mumps	2	0
			Meningitis mumps	5	0
			Mumps	271	1
			Orchitis mumps	2	0
		Parvoviral infections	Erythema infectiosum	1	0
		Respiratory syncytial viral infections	Respiratory syncytial virus infection	2	0
		Rubella viral infections	Encephalomyelitis rubella	1	0
			Rubella	55	0
		Rubeola viral infections	Measles	256	0
			Measles post vaccine	12	0
			Pneumonia measles	1	1
		Viral infections NEC	Bronchiolitis	3	0
			Ear infection viral	1	0
			Encephalitis viral	2	0
			Gastroenteritis viral	2	0
			Gianotti-Crosti syndrome	2	0
			Meningitis viral	15	0
			Pneumonia viral	1	0
			Vestibular neuronitis	1	0
			Viral infection	15	0
			Viral myocarditis	2	1
			Viral rash	11	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Viral tonsillitis	2	0
			Viral upper respiratory tract infection	2	0
Injury, poisoning and procedural complications	Bone and joint injuries	Limb fractures and dislocations	Foot fracture	1	0
	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	67	0
			Exposure via breast milk	2	0
			Foetal exposure during pregnancy	39	0
			Maternal exposure before pregnancy	14	0
			Maternal exposure during pregnancy	1	0
			Maternal exposure timing unspecified	3	0
		Occupational exposures	Occupational exposure to product	1	0
		Pathways and sources of exposure	Exposure via skin contact	1	0
	Injuries by physical agents	Conditions caused by cold	Chillblains	1	0
	Injuries NEC	Cerebral injuries NEC	Craniocerebral injury	1	0
		Cranial nerve injuries	Optic nerve injury	1	0
		Eye injuries NEC	Eye contusion	1	0
		Nerve injuries NEC	Nerve injury	2	0
		Non-site specific injuries NEC	Fall	10	0
			Injury	1	0
			Product package associated injury	1	0
		Reproductive system and breast injuries	Perineal injury	2	0
		Site specific injuries NEC	Central nervous system injury	1	0
			Head injury	1	0
		Skin injuries NEC	Contusion	44	0
			Scar	2	0
			Skin laceration	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Medication errors and other product use errors and issues	Accidental exposures to product	Accidental exposure to product	2	0
		Medication errors, product use errors and issues NEC	Inadequate aseptic technique in use of product	2	0
			Medication error	18	0
			Poor quality device used	1	0
			Product use in unapproved indication	3	0
			Vaccination error	3	0
			Wrong technique in product usage process	3	0
		Product administration errors and issues	Accidental underdose	1	0
			Booster dose missed	2	0
			Contraindicated product administered	1	0
			Expired product administered	3	0
			Extra dose administered	3	0
			Inappropriate schedule of product administration	15	0
			Incomplete course of vaccination	3	0
			Incorrect dose administered	2	0
			Incorrect dose administered by product	1	0
			Product administered at inappropriate site	3	0
			Product administered to patient of inappropriate age	2	0
			Product administration error	1	0
			Wrong patient received product	1	0
			Wrong product administered	5	0
		Product monitoring errors and issues	Labelled drug-disease interaction medication error	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Labelled drug-drug interaction issue	1	0
			Labelled drug-drug interaction medication error	1	0
		Product storage errors and issues in the product use system	Product storage error	1	0
	Off label uses and intentional product misuses/use issues	Intentional product use issues	Intentional dose omission	1	0
	Procedural related injuries and complications NEC	Vaccination related complications	Immunisation reaction	4	0
			Vaccination complication	1	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	6	0
		Heart rate and pulse investigations	Heart rate	1	0
			Heart rate abnormal	2	0
			Heart rate decreased	10	0
			Heart rate increased	13	0
			Heart rate irregular	5	0
			Pulse abnormal	6	0
			Radial pulse abnormal	1	0
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	3	0
			Blood pressure increased	10	0
	Endocrine investigations (incl sex hormones)	Pituitary analyses anterior	Blood thyroid stimulating hormone increased	1	0
	Enzyme investigations NEC	Skeletal and cardiac muscle analyses	Blood creatine phosphokinase increased	1	0
		Tissue enzyme analyses NEC	Blood alkaline phosphatase increased	2	0
	Foetal and neonatal investigations	Foetal and neonatal diagnostic procedures	Foetal heart rate decreased	2	0
			Foetal monitoring abnormal	3	0
	Gastrointestinal investigations	Digestive enzymes	Amylase increased	1	0
	Haematology investigations (incl blood groups)	Haematological analyses NEC	Red blood cell sedimentation rate increased	3	0
		Platelet analyses	Platelet count abnormal	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Platelet count decreased	10	0
		Red blood cell analyses	Haemoglobin S	1	0
		White blood cell analyses	Lymphocyte morphology abnormal	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Liver function test abnormal	2	0
	Immunology and allergy investigations	Autoimmunity analyses	Rheumatoid factor increased	1	0
		Immunoglobulin analyses	Blood immunoglobulin G increased	1	0
		Immunology analyses NEC	Antibody test negative	1	0
			Immunology test abnormal	1	0
		Immunology skin tests NEC	Skin test positive	2	0
	Investigations, imaging and histopathology procedures NEC	Investigations NEC	Blood test abnormal	1	0
			Quality of life decreased	1	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Carbon dioxide increased	1	0
			Oxygen saturation decreased	4	0
		Carbohydrate tolerance analyses (incl diabetes)	Blood glucose decreased	3	0
			Blood glucose fluctuation	1	0
			Blood glucose increased	1	0
	Microbiology and serology investigations	Virus identification and serology	Measles antibody negative	3	0
			Measles antibody positive	1	0
			Morbillivirus test positive	1	0
			Mumps antibody test negative	4	0
			Rubella antibody negative	8	0
			Rubella antibody positive	1	0
			Rubivirus test positive	1	0
			Rubulavirus test positive	1	0
	Neurological, special senses and psychiatric investigations	Cerebrospinal fluid tests (excl microbiology)	CSF cell count increased	1	0
			CSF test abnormal	1	0
		Neurologic diagnostic procedures	Electroencephalogram abnormal	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature	5	0
			Body temperature abnormal	4	0
			Body temperature decreased	8	0
			Body temperature fluctuation	6	0
			Body temperature increased	150	0
			Breath sounds abnormal	2	0
			Grip strength decreased	1	0
			Head circumference abnormal	1	0
			Head lag	1	0
			Lymph node palpable	1	0
			Respiratory rate decreased	1	0
			Respiratory rate increased	8	0
			Skin temperature	1	0
			Weight decreased	8	0
			Weight increased	1	0
	Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein increased	6	0
	Renal and urinary tract investigations and urinalyses	Urinalysis NEC	Protein urine	1	0
Urinary tract function analyses NEC		Urine output decreased	2	0	
Toxicology and therapeutic drug monitoring	Toxicology laboratory analyses	Blood aluminium increased	1	0	
		Heavy metal increased	1	0	
Metabolism and nutrition disorders	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Metabolic acidosis	3	0
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	399	0
			Diet refusal	1	0
			Food refusal	4	0
			Hyperphagia	1	0
			Hypophagia	7	0
			Increased appetite	1	0
	General nutritional disorders NEC		Abnormal loss of weight	5	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Failure to thrive	1	0
			Feeding disorder	7	0
			Food aversion	3	0
			Poor feeding infant	9	0
			Weight gain poor	1	0
	Bone, calcium, magnesium and phosphorus metabolism disorders	Calcium metabolism disorders	Hypocalcaemia	1	0
	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	9	0
		Fluid intake increased	Polydipsia	1	0
		Sodium imbalance	Hyponatraemia	4	0
		Total fluid volume decreased	Dehydration	9	0
		Total fluid volume increased	Fluid retention	2	0
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	3	0
			Food intolerance	7	0
		Sugar intolerance (excl glucose intolerance)	Lactose intolerance	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Diabetes mellitus	11	0
			Type 1 diabetes mellitus	6	0
		Hypoglycaemic conditions NEC	Hypoglycaemia	2	0
	Iron and trace metal metabolism disorders	Iron deficiencies	Iron deficiency	1	0
	Metabolism disorders NEC	Cell metabolism disorders NEC	Mitochondrial cytopathy	1	0
		Metabolic disorders NEC	Metabolic disorder	1	0
	Protein and amino acid metabolism disorders NEC	Protein metabolism disorders NEC	Hyperammonaemia	1	0
	Vitamin related disorders	Fat soluble vitamin deficiencies and disorders	Vitamin D deficiency	1	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone disorders NEC	Exostosis	1	0
		Bone related signs and symptoms	Bone pain	2	0
			Pain in jaw	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Pubic pain	1	0
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Myofascitis	1	0
			Polymyalgia rheumatica	1	0
		Lupus erythematosus (incl subtypes)	Systemic lupus erythematosus	1	0
	Joint disorders	Arthropathies NEC	Arthritis	21	0
			Arthropathy	9	0
		Joint related signs and symptoms	Arthralgia	127	0
			Joint effusion	1	0
			Joint noise	2	0
			Joint stiffness	11	0
			Joint swelling	23	0
		Osteoarthropathies	Osteoarthritis	2	0
		Rheumatoid arthropathies	Juvenile idiopathic arthritis	5	0
			Rheumatoid arthritis	2	0
		Spondyloarthropathies	Arthritis reactive	2	0
	Muscle disorders	Muscle pains	Myalgia	44	0
		Muscle related signs and symptoms NEC	Diastasis recti abdominis	1	0
			Muscle atrophy	1	0
			Muscle fatigue	1	0
			Muscle spasms	7	0
			Muscle swelling	1	0
			Muscle tightness	3	0
			Muscle twitching	16	0
		Muscle tone abnormalities	Floppy infant	8	0
			Muscle rigidity	6	0
			Nuchal rigidity	1	0
			Torticollis	1	0
			Trismus	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Muscle weakness conditions	Muscular weakness	30	0
	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)	Extremity deformities	Foot deformity	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Growth retardation	1	0
			Limb mass	1	0
			Mobility decreased	6	0
			Musculoskeletal stiffness	27	0
			Posture abnormal	3	0
			Toe walking	1	0
			Weight bearing difficulty	19	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	22	0
			Limb discomfort	9	0
			Musculoskeletal chest pain	2	0
			Musculoskeletal pain	1	0
			Neck pain	22	0
			Pain in extremity	107	0
		Soft tissue disorders NEC	Groin pain	2	0
			Neck mass	1	0
	Tendon, ligament and cartilage disorders	Cartilage disorders	Costochondritis	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatobiliary neoplasms malignant and unspecified	Hepatoblastomas	Hepatoblastoma	1	0
	Leukaemias	Leukaemias acute lymphocytic	Acute lymphocytic leukaemia	1	0
	Miscellaneous and site unspecified neoplasms benign	Cardiovascular neoplasms benign	Haemangioma	1	0
	Reproductive neoplasms female benign	Reproductive neoplasms female benign NEC	Benign hydatidiform mole	1	0
	Skin neoplasms malignant and unspecified	Skin neoplasms malignant and unspecified (excl melanoma)	Neoplasm skin	1	0
Nervous system disorders	Central nervous system infections and inflammations	Central nervous system inflammatory disorders NEC	Arachnoiditis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Encephalitis NEC	Noninfective encephalitis	2	0
		Myelitis (incl infective)	Myelitis transverse	4	0
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral infarction	1	0
			Cerebrovascular accident	1	0
		Central nervous system vascular disorders NEC	Brain hypoxia	1	0
			Vertebrobasilar insufficiency	1	0
	Cranial nerve disorders (excl neoplasms)	Eye movement disorders	Vlth nerve paralysis	3	0
		Facial cranial nerve disorders	Bell's palsy	6	0
			Facial paralysis	8	0
			Facial spasm	2	0
		Mixed cranial nerve disorders	Bulbar palsy	1	0
		Olfactory nerve disorders	Anosmia	1	0
			Parosmia	1	0
		Optic nerve disorders NEC	Optic neuritis	1	0
	Demyelinating disorders	Demyelinating disorders NEC	Acute disseminated encephalomyelitis	1	0
	Encephalopathies	Encephalopathies NEC	Encephalopathy	30	0
			Encephalopathy neonatal	1	0
			Hypoxic-ischaemic encephalopathy	1	0
			Opsoclonus myoclonus	1	0
	Headaches	Headaches NEC	Headache	154	0
			Sinus headache	2	0
		Migraine headaches	Migraine	10	0
	Increased intracranial pressure and hydrocephalus	Hydrocephalic conditions	Hydrocephalus	2	0
		Increased intracranial pressure disorders	Brain oedema	1	1
			Vasogenic cerebral oedema	1	0
	Mental impairment disorders	Intellectual disabilities	Intellectual disability	2	0
		Memory loss (excl dementia)	Amnesia	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Mental impairment (excl dementia and memory loss)	Cognitive disorder	6	0
			Disturbance in attention	11	0
			Mental impairment	4	0
	Movement disorders (incl parkinsonism)	Choreiform movements	Chorea	2	0
		Dyskinesias and movement disorders NEC	Akinesia	2	0
			Clumsiness	3	0
			Dyskinesia	13	0
			Extrapyramidal disorder	1	0
			Fine motor delay	1	0
			Fine motor skill dysfunction	2	0
			Hyperkinesia	3	0
			Hypokinesia	8	0
			Movement disorder	2	0
			Psychomotor hyperactivity	16	0
		Dystonias	Dystonia	1	0
			Opisthotonus	3	0
		Paralysis and paresis (excl cranial nerve)	Diplegia	1	0
			Hemiparesis	10	0
			Hemiplegia	2	0
			Monoplegia	3	0
			Paralysis	11	0
			Paresis	1	0
		Tremor (excl congenital)	Tremor	52	0
	Neurological disorders NEC	Abnormal reflexes	Areflexia	1	0
		Coma states	Coma	1	0
		Coordination and balance disturbances	Ataxia	24	0
			Balance disorder	25	0
			Cerebellar ataxia	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Cerebellar syndrome	1	0
			Coordination abnormal	10	0
			Dysstasia	4	0
			Hand-eye coordination impaired	1	0
			Nystagmus	1	0
		Cortical dysfunction NEC	Aphasia	25	0
			Dyslexia	1	0
			Dyspraxia	3	0
			Sensory processing disorder	3	0
		Disturbances in consciousness NEC	Altered state of consciousness	2	0
			Consciousness fluctuating	2	0
			Depressed level of consciousness	9	0
			Lethargy	149	0
			Loss of consciousness	35	0
			Somnolence	107	0
			Syncope	109	0
		Nervous system disorders NEC	Cerebral disorder	1	0
			Nervous system disorder	7	0
			Neurodegenerative disorder	1	0
			Psychomotor skills impaired	1	0
		Neurological signs and symptoms NEC	Brain fog	1	0
			Decorticate posture	1	0
			Dizziness	79	0
			Dizziness postural	2	0
			Drooling	4	0
			Exaggerated startle response	1	0
			Head discomfort	3	0
			Hyporesponsive to stimuli	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Inability to crawl	6	0
			Infant irritability	6	0
			Meningism	8	0
			Myoclonus	6	0
			Neurological decompensation	2	0
			Neurological symptom	3	0
			Pleocytosis	1	0
			Presyncope	23	0
			Slow response to stimuli	1	0
			Unresponsive to stimuli	34	0
		Paraesthesias and dysaesthesias	Burning sensation	3	0
			Dysaesthesia	1	0
			Hyperaesthesia	3	0
			Hypoaesthesia	22	0
			Paraesthesia	36	0
		Sensory abnormalities NEC	Dysgeusia	6	0
			Hypogeusia	1	0
			Neuralgia	3	0
			Restless legs syndrome	1	0
			Sensory disturbance	5	0
			Sensory loss	5	0
		Speech and language abnormalities	Dysarthria	3	0
			Repetitive speech	1	0
			Slow speech	1	0
			Speech disorder	18	0
			Speech disorder developmental	17	0
	Neuromuscular disorders	Muscle tone abnormal	Hypotonia	44	0
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Muscle spasticity	1	0
			Neuromyopathy	1	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	6	1
		Mononeuropathies	Mononeuropathy multiplex	1	0
		Peripheral neuropathies NEC	Neuralgic amyotrophy	1	0
			Neuropathy peripheral	4	0
			Polyneuropathy	3	0
	Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	6	0
		Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	27	0
		Partial complex seizures	Focal dyscognitive seizures	3	0
			Temporal lobe epilepsy	2	0
		Seizures and seizure disorders NEC	Convulsion in childhood	1	0
			Epilepsy	32	0
			Febrile convulsion	207	0
			Frontal lobe epilepsy	1	0
			Idiopathic generalised epilepsy	2	0
			Myoclonic epilepsy	1	0
			Neonatal seizure	1	0
			Partial seizures	10	0
			Seizure	306	0
			Seizure anoxic	3	0
			Seizure cluster	1	0
			Seizure like phenomena	2	0
			Status epilepticus	9	0
			Tonic convulsion	2	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	8	0
		Sleep disturbances NEC	Sleep deficit	1	0
	Spinal cord and nerve root disorders	Lumbar spinal cord and nerve root disorders	Sciatica	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Pregnancy, puerperium and perinatal conditions	Structural brain disorders	Structural brain disorders NEC	Brain injury	9	0
			Cerebral atrophy	2	0
	Abortions and stillbirth	Abortion related conditions and complications	Anembryonic gestation	1	0
		Abortions not specified as induced or spontaneous	Abortion missed	2	0
		Abortions spontaneous	Abortion spontaneous	39	0
			Abortion threatened	2	0
			Imminent abortion	1	0
		Stillbirth and foetal death	Foetal death	1	1
			Stillbirth	3	3
	Foetal complications	Foetal complications NEC	Foetal distress syndrome	1	0
			Foetal hypokinesia	2	0
		Foetal growth complications	Foetal growth restriction	6	0
		Foetal position and presentation abnormalities	Breech presentation	4	0
			Face presentation	1	0
			High foetal head	1	0
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature delivery	3	0
			Premature labour	2	0
			Premature rupture of membranes	1	0
			Prolonged labour	9	0
		Maternal complications of delivery NEC	Breech delivery	1	0
		Maternal complications of labour NEC	Labour complication	5	0
	Maternal complications of pregnancy	Haemorrhagic complications of pregnancy	Premature separation of placenta	2	0
		Hypertension associated disorders of pregnancy	Gestational hypertension	1	0
			Pre-eclampsia	4	0
		Maternal complications of pregnancy NEC	Complication of pregnancy	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Morning sickness	1	0
		Pregnancy complicated by maternal disorders	Gestational diabetes	1	0
	Neonatal and perinatal conditions	Gestational age and weight conditions	Low birth weight baby	1	0
			Premature baby	7	0
		Neonatal gastrointestinal disorders	Meconium increased	1	0
		Neonatal hepatobiliary disorders	Jaundice neonatal	1	0
	Placental, amniotic and cavity disorders (excl haemorrhages)	Amniotic fluid and cavity disorders of pregnancy NEC	Oligohydramnios	1	0
	Postpartum and puerperal disorders	Postpartum complications NEC	Postpartum haemorrhage	2	0
	Pregnancy, labour, delivery and postpartum conditions	High risk pregnancies	High risk pregnancy	1	0
		Multiple pregnancies	Multiple pregnancy	2	0
		Normal newborn status	Normal newborn	1	0
		Normal pregnancy, labour and delivery	Live birth	1	0
			Pregnancy	5	0
		Unintended pregnancies	Unintended pregnancy	1	0
Product issues	Device issues	Device issues NEC	Device connection issue	2	0
		Device physical property and chemical issues	Needle issue	2	0
			Syringe issue	2	0
	Product quality, supply, distribution, manufacturing and quality system issues	Product packaging issues	Product packaging issue	1	0
		Product quality issues NEC	Product complaint	4	0
			Product quality issue	3	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety disorders NEC	Separation anxiety disorder	2	0
		Anxiety symptoms	Agitation	19	0
			Anxiety	19	0
			Nervousness	10	0
			Stress	1	0
		Fear symptoms and phobic disorders (incl social phobia)	Fear	3	0
			Social anxiety disorder	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Obsessive-compulsive disorders and symptoms	Body dysmorphic disorder	1	0
			Obsessive-compulsive disorder	1	0
			Obsessive-compulsive symptom	1	0
			Trichotillomania	1	0
		Panic attacks and disorders	Panic attack	4	0
	Changes in physical activity	Decreased physical activity levels	Catatonia	1	0
		Increased physical activity levels	Restlessness	23	0
		Stereotypies and automatisms	Bruxism	1	0
			Head banging	7	0
			Posturing	1	0
			Stereotypy	2	0
		Tic disorders	Tic	2	0
	Cognitive and attention disorders and disturbances	Attention deficit and disruptive behaviour disorders	Attention deficit hyperactivity disorder	9	0
		Learning disorders	Learning disability	3	0
			Learning disorder	3	0
	Communication disorders and disturbances	Communications disorders	Communication disorder	3	0
			Mutism	2	0
		Speech articulation and rhythm disturbances	Dysphemia	3	0
			Lack of spontaneous speech	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	13	0
			Disorientation	14	0
		Deliria	Delirium	7	0
	Depressed mood disorders and disturbances	Depressive disorders	Depression	12	0
		Mood alterations with depressive symptoms	Anhedonia	1	0
			Decreased interest	2	0
			Depressed mood	12	0
			Tearfulness	15	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	144	1
	Dissociative disorders	Dissociative states	Depersonalisation/derealisation disorder	4	0
			Dissociation	2	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	11	0
			Hallucination, visual	3	0
		Perception disturbances NEC	Time perception altered	1	0
		Thinking disturbances	Intrusive thoughts	1	0
			Thinking abnormal	3	0
	Eating disorders and disturbances	Eating disorders NEC	Eating disorder	4	0
			Selective eating disorder	1	0
	Mood disorders and disturbances NEC	Affect alterations NEC	Affect lability	3	0
			Flat affect	1	0
		Emotional and mood disturbances NEC	Anger	2	0
			Dysphoria	1	0
			Emotional disorder	4	0
			Emotional distress	22	0
			Frustration tolerance decreased	1	0
			Irritability	242	0
			Mood altered	6	0
			Morose	1	0
		Fluctuating mood symptoms	Mood swings	1	0
		Mood disorders NEC	Affective disorder	1	0
			Apathy	3	0
			Listless	13	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	15	0
			Antisocial behaviour	2	0
			Attention-seeking behaviour	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Personality change	10	0
			Self-destructive behaviour	1	0
			Social avoidant behaviour	11	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	39	0
			Behaviour disorder	12	0
			Breath holding	4	0
			Regressive behaviour	1	0
			Staring	7	0
		Psychiatric symptoms NEC	Decreased eye contact	8	0
	Psychiatric disorders NEC	Infancy, childhood and adolescence psychiatric disorders NEC	Social (pragmatic) communication disorder	1	0
		Mental disorders NEC	Mental disorder	6	0
			Mental status changes	2	0
		Psychiatric elimination disorders	Enuresis	3	0
	Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Psychotic disorder	2	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Initial insomnia	1	0
			Insomnia	72	0
			Middle insomnia	4	0
		Dyssomnias	Poor quality sleep	13	0
		Parasomnias	Abnormal dreams	1	0
			Nightmare	4	0
			Sleep terror	4	0
		Sleep disorders NEC	Sleep disorder	32	0
	Somatic symptom and related disorders	Somatic symptom disorders	Conversion disorder	1	0
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour	Intentional self-injury	1	0
			Self-injurious ideation	1	0
Renal and urinary disorders	Bladder and bladder neck disorders (excl calculi)	Bladder disorders NEC	Bladder disorder	1	0
		Mvoneurogenic bladder disorders	Bladder dysfunction	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Nephropathies	Glomerulonephritis and nephrotic syndrome	Nephrotic syndrome	7	0
		Nephritis NEC	Tubulointerstitial nephritis	1	0
		Nephropathies and tubular disorders NEC	Renal tubular disorder	2	0
	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
			Oliguria	1	0
			Renal impairment	1	0
			Renal injury	1	0
		Renal structural abnormalities and trauma	Pyelocaliectasis	1	0
		Renal vascular and ischaemic conditions	Renal tubular necrosis	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Dysuria	1	0
			Incontinence	3	0
			Micturition disorder	1	0
			Micturition frequency decreased	1	0
			Micturition urgency	1	0
			Pollakiuria	2	0
			Urinary incontinence	12	0
			Urinary retention	2	0
		Urinary abnormalities	Chromaturia	1	0
			Haematuria	5	0
			Proteinuria	2	0
		Urinary tract signs and symptoms NEC	Renal pain	3	0
Reproductive system and breast disorders	Breast disorders	Breast disorders NEC	Breast enlargement	1	0
		Breast infections and inflammations	Nipple inflammation	1	0
		Breast signs and symptoms	Breast pain	1	0
			Breast swelling	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Cervix disorders (excl infections and inflammations)	Cervix neoplasms	Cervical polyp	1	0
	Male reproductive tract infections and inflammations	Penile and scrotal infections and inflammations	Balanoposthitis	1	0
	Menstrual cycle and uterine bleeding disorders	Menstruation and uterine bleeding NEC	Intermenstrual bleeding	1	0
			Menstrual disorder	2	0
		Menstruation with decreased bleeding	Menstruation delayed	3	0
			Menstruation with increased bleeding	Heavy menstrual bleeding	2
	Penile and scrotal disorders (excl infections and inflammations)	Scrotal disorders NEC	Scrotal swelling	3	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Genital pain	1	0
			Genital rash	3	0
			Genital swelling	1	0
			Oedema genital	1	0
			Pelvic pain	2	0
	Sexual function and fertility disorders	Erection and ejaculation conditions and disorders	Erectile dysfunction	1	0
	Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular disorder	1	0
			Testicular pain	6	0
			Testicular swelling	15	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vaginal haemorrhage	7	0
		Vulvovaginal signs and symptoms	Vulvovaginal discomfort	1	0
	Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	16
Bronchospasm				11	0
Wheezing				26	0
Lower respiratory tract disorders (excl obstruction and infection)		Lower respiratory tract inflammatory and immunologic conditions	Alveolitis	1	0
			Lower respiratory tract inflammation	1	0
			Pneumonitis	5	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Pneumonitis aspiration	1	0
		Parenchymal lung disorders NEC	Interstitial lung disease	2	1
			Lung consolidation	1	0
			Organising pneumonia	1	0
			Pulmonary alveolar haemorrhage	1	0
			Pulmonary fibrosis	1	0
		Pulmonary oedemas	Acute lung injury	1	0
			Acute pulmonary oedema	1	0
			Acute respiratory distress syndrome	4	1
			Pulmonary congestion	1	0
			Pulmonary oedema	2	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Neonatal respiratory distress syndrome	3	0
		Newborn respiratory disorders NEC	Bronchopulmonary dysplasia	1	0
			Transient tachypnoea of the newborn	1	0
	Pleural disorders	Pleural conditions NEC	Pleural adhesion	1	0
		Pneumothorax and pleural effusions NEC	Pleural effusion	3	0
	Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	1	0
		Vascular pulmonary disorders NEC	Pulmonary arteriopathy	2	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	2	0
			Apnoeic attack	3	0
			Dyspnoea	66	0
			Hyperventilation	3	0
			Hypopnoea	10	0
			Irregular breathing	1	0
			Obstructive sleep apnoea syndrome	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Respiration abnormal	4	0
			Respiratory arrest	16	1
			Respiratory depression	1	0
			Respiratory distress	6	0
			Sleep apnoea syndrome	3	0
			Tachypnoea	2	0
		Conditions associated with abnormal gas exchange	Asphyxia	2	0
			Cyanosis central	3	0
			Hypoxia	3	0
			Respiratory gas exchange disorder	2	0
		Coughing and associated symptoms	Cough	185	0
			Haemoptysis	2	0
			Productive cough	3	0
		Respiratory failures (excl neonatal)	Acute respiratory failure	1	0
			Respiratory failure	6	2
		Respiratory tract disorders NEC	Aspiration	2	1
			Respiratory disorder	5	0
			Respiratory tract irritation	1	0
			Respiratory tract oedema	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Hiccups	1	0
			Pulmonary haemorrhage	1	0
			Rales	1	0
		Respiratory signs and symptoms NEC	Respiratory symptom	1	0
		Upper respiratory tract signs and symptoms	Aphonia	3	0
			Catarrh	4	0
			Choking	1	0
			Dry throat	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Dysphonia	3	0
			Increased viscosity of upper respiratory secretion	1	0
			Nasal discharge discolouration	1	0
			Oropharyngeal discomfort	2	0
			Oropharyngeal pain	71	0
			Rhinorrhoea	87	0
			Sinus pain	1	0
			Sneezing	5	0
			Snoring	2	0
			Throat irritation	3	0
			Throat tightness	3	0
			Upper-airway cough syndrome	2	0
			Yawning	1	0
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Stridor	8	0
		Nasal congestion and inflammations	Nasal congestion	18	0
		Nasal disorders NEC	Epistaxis	26	0
			Nasal pruritus	1	0
		Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	2	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal disorder	1	0
			Pharyngeal erythema	8	0
			Pharyngeal inflammation	2	0
			Pharyngeal oedema	1	0
			Pharyngeal paraesthesia	1	0
			Pharyngeal swelling	12	0
			Pharyngeal ulceration	1	0
			Tonsillar hypertrophy	6	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Skin and subcutaneous tissue disorders			Tonsillar inflammation	2	0
			Velopharyngeal incompetence	2	0
	Angioedema and urticaria	Angioedemas	Angioedema	23	0
		Urticarias	Mechanical urticaria	2	0
			Urticaria	338	0
	Cornification and dystrophic skin disorders	Hyperkeratoses	Hyperkeratosis	2	0
			Lichenoid keratosis	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	41	0
			Blood blister	2	0
			Dermatitis bullous	13	0
			Erythema multiforme	68	0
			Stevens-Johnson syndrome	3	0
			Toxic epidermal necrolysis	1	0
		Connective tissue disorders	Dermatomyositis	1	0
		Dermal and epidermal conditions NEC	Dry skin	11	0
			Macule	1	0
			Pain of skin	5	0
			Papule	30	0
			Scab	5	0
			Sensitive skin	1	0
			Skin burning sensation	3	0
			Skin discolouration	16	0
			Skin disorder	5	0
			Skin fissures	1	0
			Skin induration	8	0
			Skin lesion	5	0
			Skin necrosis	1	0
			Skin reaction	18	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Skin tightness	4	0
			Skin warm	42	0
			Skin weeping	1	0
		Dermatitis and eczema	Dermatitis	4	0
			Dermatitis allergic	36	0
			Dermatitis atopic	5	0
			Dermatitis contact	2	0
			Dermatitis diaper	13	0
			Eczema	76	0
			Eczema infantile	4	0
			Eczema weeping	1	0
			Seborrhoeic dermatitis	1	0
			Skin irritation	4	0
		Dermatitis ascribed to specific agent	Drug eruption	4	0
			Drug reaction with eosinophilia and systemic symptoms	1	0
			Toxic skin eruption	1	0
		Erythemas	Erythema	288	0
		Exfoliative conditions	Dermatitis exfoliative	2	0
			Dermatitis exfoliative generalised	1	0
			Skin exfoliation	10	0
		Papulosquamous conditions	Erythema annulare	1	0
			Erythema marginatum	1	0
			Lichen sclerosus	1	0
			Pityriasis rosea	1	0
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	1	0
		Pruritus NEC	Pruritus	127	0
		Psoriatic conditions	Guttate psoriasis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Pustular conditions	Rash follicular	1	0
		Rashes, eruptions and exanthems NEC	Rash	1,219	0
			Rash erythematous	140	0
			Rash macular	120	0
			Rash maculo-papular	125	0
			Rash morbilliform	425	0
			Rash papular	56	0
			Rash pruritic	40	0
			Rash rubelliform	21	0
			Rash scarlatiniform	1	0
			Rash vesicular	16	0
		Scaly conditions	Pityriasis	1	0
		Skin injuries and mechanical dermatoses	Decubitus ulcer	1	0
	Pigmentation disorders	Hypopigmentation disorders	Vitiligo	2	0
		Pigmentation changes NEC	Pigmentation disorder	1	0
Skin and subcutaneous tissue disorders NEC		Panniculitides	Erythema nodosum	5	0
		Skin and subcutaneous conditions NEC	Skin mass	1	0
		Skin and subcutaneous tissue ulcerations	Skin ulcer	1	0
Skin appendage conditions		Acnes	Acne	3	0
		Alopecias	Alopecia	6	0
			Alopecia totalis	1	0
		Apocrine and eccrine gland disorders	Cold sweat	30	0
			Hyperhidrosis	46	0
			Miliaria	2	0
			Night sweats	5	0
		Nail and nail bed conditions (excl infections and infestations)	Nail discolouration	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Pilar disorders NEC	Hair disorder	1	0
			Hair growth abnormal	1	0
	Skin vascular abnormalities	Purpura and related conditions	Ecchymosis	1	0
			Henoch-Schonlein purpura	12	0
			Petechiae	30	0
			Purpura	21	0
		Skin vasculitides	Nodular vasculitis	1	0
			Vasculitic rash	2	0
		Skin vasomotor conditions	Livedo reticularis	5	0
Social circumstances	Family issues	Family and partner issues	Multiple birth sibling	2	0
	Lifestyle issues	Disability issues	Bedridden	1	0
			Immobile	5	0
			Impaired work ability	2	0
			Mental disability	2	0
			Physical disability	1	0
			Walking disability	2	0
		Educational issues	Educational problem	1	0
		Social issues NEC	Contraindication to vaccination	5	0
Surgical and medical procedures	Endocrine gland therapeutic procedures	Hormonal therapeutic procedures NEC	Steroid therapy	1	0
	Haematological and lymphoid tissue therapeutic procedures	Blood and blood product treatment	Transfusion	1	0
		Lymphoid tissue therapeutic procedures	Splenectomy	1	0
	Head and neck therapeutic procedures	Middle ear therapeutic procedures	Ear tube insertion	1	0
		Tonsillar therapeutic procedures	Adenoidectomy	1	0
			Tonsillectomy	1	0
	Obstetric and gynaecological therapeutic procedures	Induced abortions	Abortion induced	6	0
		Obstetric therapeutic procedures	Caesarean section	20	0
			Episiotomy	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Forceps delivery	1	0
			Labour induction	1	0
			Labour stimulation	1	0
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Surgery	1	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	8	0
			Poor peripheral circulation	2	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	17	0
			Peripheral circulatory failure	1	0
			Shock	6	0
		Vascular hypotensive disorders	Hypotension	7	0
	Vascular disorders NEC	Non-site specific vascular disorders NEC	Superficial vein prominence	1	0
			Vasodilatation	1	0
		Peripheral vascular disorders NEC	Cyanosis	57	0
			Flushing	28	0
			Hot flush	5	0
		Site specific vascular disorders NEC	Pallor	158	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	8	0
	Vascular hypertensive disorders	Accelerated and malignant hypertension	Accelerated hypertension	1	0
		Vascular hypertensive disorders NEC	Hypertension	7	0
	Vascular infections and inflammations	Arterial infections and inflammations	Arteritis	1	0
			Giant cell arteritis	1	0
			Kawasaki's disease	9	0
		Vasculitides NEC	Vasculitis	2	0
Total				8,228	53