

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Report Count	Fatal Count
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemia deficiencies	Iron deficiency anaemia	1	
			Pernicious anaemia	2	
		Anaemias NEC	Anaemia	3	
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Increased tendency to bruise	1	
	Haematological disorders NEC	Haematological disorders	Mast cell activation syndrome	1	
			Methaemoglobinaemia	1	
	Haemolyses and related conditions	Anaemias haemolytic NEC	Haemolytic anaemia	1	
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	7	
			Lymphadenopathy	24	
	White blood cell disorders	Eosinophilic disorders	Eosinophilia	3	
		Neutropenias	Neutropenia	1	
Cardiac disorders	Cardiac arrhythmias	Cardiac conduction disorders	Atrioventricular block	2	
			Atrioventricular block complete	2	
		Rate and rhythm disorders NEC	Arrhythmia	6	
			Bradycardia	1	
			Cardiac flutter	4	
			Extrasystoles	2	
			Postural orthostatic tachycardia syndrome	1	

			Tachycardia	30	
			Atrial fibrillation	8	
			Atrial flutter	2	
			Supraventricular tachycardia	3	
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	6	2
			Ventricular tachycardia	3	
		Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	189	
		Coronary artery disorders	Ischaemic coronary artery disorders	Acute myocardial infarction	6
				Myocardial infarction	10
				Myocardial ischaemia	1
		Heart failures	Heart failures NEC	Cardiac failure	3
				Cardiac failure acute	1
		Myocardial disorders	Cardiomyopathies	Cardiomyopathy	1
			Myocardial disorders NEC	Cardiac sarcoidosis	1
	Congenital, familial and genetic disorders	Cardiac and vascular disorders congenital	Cardiac disorders congenital NEC	Heart disease congenital	1
			Cardiac septal defects congenital	Atrial septal defect	1
				Ventricular septal defect	1
		Congenital and hereditary disorders NEC	Congenital disorders NEC	Congenital anomaly	1

	Neurological disorders congenital	Neurological disorders congenital NEC	Familial hemiplegic migraine	1	
	Respiratory disorders congenital	Pulmonary and bronchial disorders congenital	Pulmonary hypoplasia	1	
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear congestion	1	
			Ear pain	4	
	Hearing disorders	Hearing losses	Deafness neurosensory	1	
			Hypoacusis	3	
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Motion sickness	5	
			Tinnitus	12	
			Vertigo	11	
			Vertigo positional	1	
	Middle ear disorders (excl congenital)	Tympanic membrane disorders (excl infections)	Tympanic membrane perforation	1	
Endocrine disorders	Adrenal gland disorders	Adrenal cortical hypofunctions	Adrenal insufficiency	1	
			Adrenocortical insufficiency acute	2	
	Endocrine disorders of gonadal function	Female gonadal function disorders	Anovulatory cycle	1	
			Polycystic ovarian syndrome	1	
	Hypothalamus and pituitary gland disorders	Hypothalamic and pituitary disorders NEC	Hypophysitis	1	
	Parathyroid gland disorders	Hyperparathyroid disorders	Hyperparathyroidism primary	1	

	Thyroid gland disorders	Acute and chronic thyroiditis	Thyroiditis	1	
		Thyroid disorders NEC	Goitre	4	
			Thyroid disorder	4	
			Thyroid mass	5	
		Thyroid hyperfunction disorders	Hyperthyroidism	1	
			Thyrotoxic crisis	1	
		Thyroid hypofunction disorders	Hypothyroidism	2	
		Thyroid neoplasms	Thyroid cyst	3	
		Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	5
			Iris and ciliary body structural change, deposit and degeneration	Eye colour change	1
Eye disorders	Eye disorders NEC	Lacrimation disorders	Dry eye	7	
			Lacrimation increased	3	
		Ocular disorders NEC	Dark circles under eyes	1	
			Eye disorder	3	
			Eye oedema	1	
			Eye pain	9	
			Eye swelling	5	
			Periorbital swelling	2	
		Glaucoma and ocular hypertension	Glaucomas (excl congenital)	Angle closure glaucoma	1
		Ocular haemorrhages and vascular disorders NEC	Ocular bleeding and vascular disorders NEC	Eye haemorrhage	2

	Optic nerve bleeding and vascular disorders	Optic ischaemic neuropathy	1	
Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Blepharitis	3	
		Eyelid rash	1	
	Ocular infections, inflammations and associated manifestations	Eye inflammation	2	
		Eye pruritus	5	
		Ocular hyperaemia	3	
	Retinal, choroid and vitreous infections and inflammations	Macular oedema	1	
		Vitritis	1	
Ocular neuromuscular disorders	Eyelid movement disorders	Blepharospasm	6	
		Eyelid ptosis	1	
Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	2	
		Photophobia	1	
Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit and degeneration	Vitreous floaters	9	
	Retinal structural change, deposit and degeneration	Maculopathy	6	
		Retinal detachment	3	
		Vitreoretinal traction syndrome	1	
Retina, choroid and vitreous haemorrhages and vascular disorders	Structural change, deposit and degeneration of eye NEC	Eye degenerative disorder	2	
	Retinal bleeding and vascular disorders (excl retinopathy)	Retinal haemorrhage	1	
		Retinal ischaemia	1	

			Retinal neovascularisation	1	
			Retinal vein occlusion	1	
		Retinopathies NEC	Central serous chorioretinopathy	1	
			Diabetic retinopathy	11	
			Non-proliferative retinopathy	2	
			Retinopathy	7	
	Vision disorders	Amblyopic vision impairment	Amblyopia	1	
		Refractive and accommodative disorders	Myopia	1	
		Visual disorders NEC	Diplopia	4	
			Metamorphopsia	1	
			Vision blurred	45	
		Visual impairment and blindness (excl colour blindness)	Blindness	9	
			Blindness unilateral	4	
			Sudden visual loss	1	
			Visual acuity reduced	2	
			Visual impairment	20	
Gastrointestinal disorders	Abdominal hernias and other abdominal wall conditions	Abdominal hernias NEC	Abdominal hernia	1	
		Umbilical hernias	Umbilical hernia	1	
	Anal and rectal conditions NEC	Anal and rectal disorders NEC	Anal fissure	2	
			Anal sphincter atony	1	
		Anal and rectal pains	Proctalgia	1	

	Anal and rectal signs and symptoms	Anal spasm	1	
		Anorectal discomfort	1	
Benign neoplasms gastrointestinal	Benign neoplasms gastrointestinal (excl oral cavity)	Gastric polyps	1	
Dental and gingival conditions	Dental pain and sensation disorders	Dental discomfort	1	
		Hyperaesthesia teeth	2	
		Toothache	2	
	Gingival disorders, signs and symptoms NEC	Gingival pain	3	
	Tooth missing	Tooth loss	1	
Exocrine pancreas conditions	Acute and chronic pancreatitis	Autoimmune pancreatitis	1	
		Haemorrhagic necrotic pancreatitis	1	1
		Obstructive pancreatitis	2	
		Pancreatitis	113	1
		Pancreatitis acute	35	
		Pancreatitis chronic	1	
		Pancreatitis necrotising	3	1
	Cystic pancreatic disorders	Pancreatic cyst	2	
	Pancreatic disorders NEC	Pancreatic disorder	1	
		Pancreatic failure	1	
Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Food poisoning	2	
		Functional gastrointestinal disorder	1	
		Gastrointestinal disorder	61	

	Oesophageal disorders NEC	Oesophageal disorder	1	
Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Gastric haemorrhage	1	
	Intestinal haemorrhages	Rectal haemorrhage	14	
	Non-site specific gastrointestinal haemorrhages	Gastrointestinal haemorrhage	1	
		Haematemesis	19	
		Haematochezia	11	
		Upper gastrointestinal haemorrhage	1	
Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis	10	
		Colitis ischaemic	2	
		Colitis ulcerative	3	
	Gastritis (excl infective)	Gastritis	31	
		Gastritis haemorrhagic	1	
		Reflux gastritis	10	
	Gastrointestinal inflammatory disorders NEC	Duodenitis	3	
		Enteritis	1	
		Gastrointestinal tract irritation	1	
		Mesenteric panniculitis	1	
	Oesophagitis (excl infective)	Oesophagitis	2	
Gastrointestinal motility and	Diarrhoea (excl infective)	Diarrhoea	2,996	



defaecation conditions		Diarrhoea haemorrhagic	5	
	Gastrointestinal atonic and hypomotility disorders NEC	Constipation	3,986	
		Duodenogastric reflux	1	
		Gastric dilatation	1	
		Gastrointestinal hypomotility	1	
		Gastrooesophageal reflux disease	105	
		Impaired gastric emptying	32	
		Infrequent bowel movements	2	
		Intestinal pseudo-obstruction	1	
		Obstructive defaecation	1	
	Gastrointestinal dyskinetic disorders	Bowel movement irregularity	3	
		Change of bowel habit	1	
		Dyschezia	1	
		Gastrointestinal motility disorder	2	
	Gastrointestinal spastic and hypermotility disorders	Defaecation urgency	2	
		Frequent bowel movements	4	
		Irritable bowel syndrome	6	
		Oesophageal spasm	1	
	Non-mechanical ileus	Ileus paralytic	1	

Gastrointestinal signs and symptoms	Abdominal findings abnormal	Gastrointestinal sounds abnormal	4	
	Dyspeptic signs and symptoms	Dyspepsia	437	
		Epigastric discomfort	5	
		Eructation	345	
	Faecal abnormalities NEC	Abnormal faeces	2	
		Faecaloma	2	
		Faeces discoloured	5	
		Faeces pale	2	
	Flatulence, bloating and distension	Abdominal distension	208	
		Flatulence	206	
	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	988	
		Abdominal pain lower	7	
		Abdominal pain upper	298	
		Abdominal tenderness	1	
		Gastrointestinal pain	23	
		Oesophageal pain	1	
	Gastrointestinal signs and symptoms NEC	Abdominal discomfort	110	
		Anal incontinence	10	
		Breath odour	12	
		Dumping syndrome	1	
		Dysphagia	7	
		Odynophagia	1	
	Nausea and vomiting symptoms	Discoloured vomit	2	
		Faecal vomiting	1	
		Nausea	6,385	
		Regurgitation	2	
		Retching	5	

		Vomiting	1,421	
		Vomiting projectile	13	
	Gastrointestinal stenosis and obstruction	Small intestinal obstruction	6	
		Gastrointestinal stenosis and obstruction NEC	15	
		Intestinal obstruction	15	
	Large intestinal stenosis and obstruction	Volvulus	2	
		Large intestinal obstruction	1	
	Gastrointestinal ulceration and perforation	Gastric ulcers and perforation	1	
		Haemorrhagic erosive gastritis	1	
		Gastrointestinal ulcers and perforation, site unspecified	1	1
		Intestinal ulcers and perforation NEC	3	
		Large intestinal ulcer	1	
		Oesophageal ulcers and perforation	2	
	Gastrointestinal vascular conditions	Peptic ulcers and perforation	1	
		Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	1	
		Gastrointestinal necrosis	1	
		Gastrointestinal vascular occlusion and infarction	4	2
		Intestinal ischaemia	4	2

		Mesenteric vein thrombosis	1	
	Haemorrhoids and gastrointestinal varices (excl oesophageal)	Haemorrhoids	6	
Malabsorption conditions	Malabsorption syndromes	Coeliac disease	1	
		Steatorrhoea	6	
Oral soft tissue conditions	Oral soft tissue disorders NEC	Lip blister	2	
		Oral lichen planus	1	
	Oral soft tissue signs and symptoms	Anaesthesia oral	1	
		Hypoaesthesia oral	3	
		Lip pain	1	
		Oral discomfort	4	
		Oral pain	3	
		Paraesthesia oral	7	
	Oral soft tissue swelling and oedema	Lip swelling	8	
		Mouth swelling	1	
	Stomatitis and ulceration	Aphthous ulcer	2	
		Mouth ulceration	6	
		Stomatitis	1	
Peritoneal and retroperitoneal conditions	Peritoneal and retroperitoneal fibrosis and adhesions	Abdominal adhesions	1	
Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	46	
		Lip dry	2	
		Salivary hypersecretion	6	

General disorders and administration site conditions	Tongue conditions	Salivary gland disorders NEC	Salivary gland mass	1	
		Tongue signs and symptoms	Glossodynia	2	
			Swollen tongue	7	
			Tongue coated	1	
	Administration site reactions	Infusion site reactions	Infusion site urticaria	1	
		Injection site reactions	Injection site bruising	32	
			Injection site discharge	12	
			Injection site discomfort	3	
			Injection site dryness	1	
			Injection site erythema	31	
			Injection site haemorrhage	7	
			Injection site hypersensitivity	4	
			Injection site hypoaesthesia	2	
			Injection site induration	1	
			Injection site inflammation	4	
			Injection site injury	6	
			Injection site irritation	2	
			Injection site mass	12	
			Injection site oedema	1	
			Injection site pain	30	
			Injection site pruritus	36	
			Injection site rash	47	

		Injection site reaction	32	
		Injection site swelling	11	
		Injection site urticaria	6	
		Injection site vesicles	3	
		Injection site warmth	3	
Body temperature conditions	Febrile disorders	Pyrexia	33	
Complications associated with device	Complications associated with device NEC	Complication associated with device	1	
		Injury associated with device	2	
Fatal outcomes	Death and sudden death	Death	8	7
		Hanging	1	1
General system disorders NEC	Asthenic conditions	Asthenia	34	
		Fatigue	3,240	
		Malaise	121	
	Feelings and sensations NEC	Chills	22	
		Early satiety	1	
		Feeling abnormal	15	
		Feeling cold	37	
		Feeling hot	11	
		Feeling jittery	1	
		Feeling of body temperature change	1	
		Hangover	1	
		Hunger	28	
		Sensation of foreign body	18	
		Thirst	18	
		Thirst decreased	2	
	Gait disturbances	Gait disturbance	6	

	Loss of control of legs	1	
General signs and symptoms NEC	Condition aggravated	10	
	Crying	8	
	Energy increased	1	
	Exercise tolerance decreased	1	
	Fat tissue decreased	1	
	General physical health deterioration	2	
	Illness	275	
	Influenza like illness	9	
	Local reaction	1	
	Multiple organ dysfunction syndrome	4	1
	Peripheral swelling	20	
	Pre-existing condition improved	2	
	Premature ageing	3	
	Swelling	17	
	Swelling face	13	
	Unevaluable event	3	
Hernias NEC	Hernia	1	
	Strangulated hernia	1	
Inflammations	Inflammation	2	
Oedema NEC	Generalised oedema	1	
	Oedema	2	

Therapeutic and nontherapeutic effects (excl toxicity)	Pain and discomfort NEC	Oedema peripheral	3	
		Chest discomfort	17	
		Chest pain	26	
		Discomfort	7	
		Facial pain	1	
		Pain	65	
		Tenderness	1	
	Interactions	Drug interaction	10	
	Therapeutic and nontherapeutic responses	Adverse drug reaction	13	
		Adverse event	2	
		Drug dechallenge positive	1	
		Drug effect less than expected	3	
		Drug ineffective	42	
		Drug ineffective for unapproved indication	4	
		Drug intolerance	14	
		Drug resistance	1	
		Therapeutic product effect decreased	1	
		Therapeutic product effect variable	1	
		Therapeutic response decreased	1	
		Therapeutic response unexpected	2	



Hepatobiliary disorders			Therapy non-responder	3	
			Treatment noncompliance	5	
	Tissue disorders NEC	Healing abnormal NEC	Impaired healing	1	
		Mass conditions NEC	Cyst	2	
			Mass	2	
		Necrosis NEC	Necrosis	1	
		Ulcers NEC	Ulcer	1	
	Bile duct disorders	Bile duct infections and inflammations	Biliary colic	24	
			Cholangitis	3	
		Obstructive bile duct disorders (excl neoplasms)	Bile duct stone	1	
	Gallbladder disorders	Cholecystitis and cholelithiasis	Acute cholecystitis necrotic	2	
			Cholecystitis	29	
			Cholecystitis acute	7	
			Cholelithiasis	79	
		Gallbladder disorders NEC	Gallbladder disorder	6	
			Gallbladder polyp	3	
			Gallbladder rupture	1	
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	19	
			Jaundice cholestatic	1	
			Ocular icterus	2	
		Hepatic and hepatobiliary disorders NEC	Biloma	1	
			Hepatic lesion	1	
			Liver disorder	3	

		Hepatic failure and associated disorders	Acute hepatic failure	1	
			Hepatic failure	1	
		Hepatic fibrosis and cirrhosis	Primary biliary cholangitis	1	
		Hepatobiliary signs and symptoms	Hepatic pain	4	
		Hepatocellular damage and hepatitis NEC	Autoimmune hepatitis	1	
			Drug-induced liver injury	3	
			Hepatic steatosis	3	
			Hepatitis	3	
			Hepatotoxicity	1	
			Liver injury	11	
			Metabolic dysfunction-associated liver disease	1	
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	32	
			Type I hypersensitivity	1	
		Allergies to foods, food additives, drugs and other chemicals	Drug hypersensitivity	9	
			Food allergy	1	
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	14	
	Immune disorders NEC	Acute and chronic sarcoidosis	Sarcoidosis	1	
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Bacterial food poisoning	1	
			Cellulitis	8	

		Injection site cellulitis	1	
	Helicobacter infections	Helicobacter gastritis	1	
	Staphylococcal infections	Furuncle	3	
	Streptococcal infections	Pharyngitis streptococcal	1	
Fungal infectious disorders	Candida infections	Balanitis candida	1	
		Candida infection	3	
		Oral candidiasis	3	
		Vulvovaginal candidiasis	3	
Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Appendicitis	16	
		Appendicitis perforated	2	
		Diverticulitis	12	
		Dysentery	1	
		Gastric infection	1	
		Gastroenteritis	9	
		Large intestine infection	1	
		Pancreas infection	1	
		Perirectal abscess	1	
		Peritonitis	2	
	Dental and oral soft tissue infections	Gingivitis	1	
		Tooth abscess	1	
	Ear infections	Ear infection	1	
	Eye and eyelid infections	Conjunctivitis	1	
	Female reproductive tract infections	Vulvitis	1	

Hepatobiliary and spleen infections	Cholecystitis infective	4	
	Liver abscess	1	
Infections NEC	Abscess	1	
	Infection	3	
	Injection site infection	2	
	Localised infection	1	
	Omphalitis	1	
	Post procedural infection	1	
Lower respiratory tract and lung infections	Lower respiratory tract infection	2	
	Pneumonia	4	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	7	
	Septic shock	1	
	Urosepsis	3	
Skin structures and soft tissue infections	Blister infected	1	
	Rash pustular	1	
	Skin infection	1	
Upper respiratory tract infections	Laryngitis	1	
	Nasopharyngitis	10	
	Sinusitis	1	
	Tonsillitis	2	
Urinary tract infections	Cystitis	4	
	Emphysematous pyelonephritis	1	
	Kidney infection	5	
	Pyelonephritis	2	
	Urinary tract infection	19	

	Protozoal infectious disorders	Plasmodia infections	Malaria	1	
	Viral infectious disorders	Coronavirus infections	COVID-19	5	
		Herpes viral infections	Herpes simplex	1	
			Herpes zoster	5	
			Oral herpes	2	
		Influenza viral infections	Influenza	8	
		Rubeola viral infections	Measles	2	
		Viral infections NEC	Gastroenteritis viral	6	
			Meningitis viral	1	
			Sweating fever	2	
			Viral infection	5	
Injury, poisoning and procedural complications	Bone and joint injuries	Limb fractures and dislocations	Hand fracture	1	
			Hip fracture	1	
	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Foetal exposure during pregnancy	1	
			Maternal exposure during breast feeding	2	
			Maternal exposure during pregnancy	19	
		Poisoning and toxicity	Toxicity to various agents	2	
	Injuries by physical agents	Heat injuries (excl thermal burns)	Heat exhaustion	1	
		Radiation injuries	Sunburn	2	

		Thermal burns	Thermal burn	2	
			Thermal burns of eye	1	
	Injuries NEC	Abdominal and gastrointestinal injuries NEC	Gallbladder injury	1	
		Chest and respiratory tract injuries NEC	Foreign body in throat	2	
		Muscle, tendon and ligament injuries	Muscle rupture	1	
			Tendon rupture	1	
		Non-site specific injuries NEC	Animal bite	1	
			Fall	4	
		Site specific injuries NEC	Head injury	1	
			Limb injury	1	
		Skin injuries NEC	Contusion	22	
			Scar	1	
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Drug titration error	1	
			Medication error	98	
			Multiple use of single-use product	1	
			Prescription drug used without a prescription	18	
			Product use complaint	2	
			Product use in unapproved indication	55	
			Product use issue	7	
			Wrong dose	2	

	Wrong technique in product usage process	22	
Product administration errors and issues	Accidental overdose	2	
	Accidental underdose	12	
	Counterfeit product administered	9	
	Drug dose titration not performed	1	
	Expired product administered	6	
	Extra dose administered	17	
	Inappropriate schedule of product administration	38	
	Incorrect dose administered	31	
	Incorrect dose administered by device	6	
	Incorrect route of product administration	2	
	Lack of injection site rotation	1	
	Product dose omission issue	25	

		Product confusion errors and issues	Product appearance confusion	1	
		Product dispensing errors and issues	Product dispensing error	1	
		Product prescribing errors and issues	Product prescribing error	1	
			Product prescribing issue	2	
		Product storage errors and issues in the product use system	Product storage error	3	
		Product transcribing errors and communication issues	Product communication issue	1	
	Off label uses and intentional product misuses/use issues	Intentional product misuses	Intentional product misuse	5	
		Intentional product use issues	Intentional dose omission	1	
		Off label uses	Off label use	74	
	Overdoses and underdoses NEC	Overdoses NEC	Intentional overdose	1	
			Overdose	10	1
		Underdoses NEC	Underdose	2	
	Procedural related injuries and complications NEC	Neurological and psychiatric procedural complications	Procedural dizziness	2	



		Non-site specific procedural complications	Injection related reaction	2	
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	1	
		Cardiac function diagnostic procedures	Cardiac monitoring	1	
			Ejection fraction decreased	1	
		ECG investigations	Electrocardiogram abnormal	1	
		Heart rate and pulse investigations	Heart rate	13	
			Heart rate abnormal	2	
			Heart rate decreased	3	
			Heart rate increased	62	
			Heart rate irregular	1	
			Maximum heart rate increased	1	
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	6	
			Blood pressure increased	6	
	Cytogenetic investigations and genetic analyses	Cell marker analyses	Human epidermal growth factor receptor increased	1	
		Gene analyses	EGFR status assay	1	
	Endocrine investigations (incl sex hormones)	Adrenal cortex tests	Cortisol increased	1	
		Endocrine analyses and imaging NEC	Hormone level abnormal	1	

		Gastrointestinal, pancreatic and APUD hormone analyses	Blood calcitonin increased	2	
			Blood insulin	1	
		Reproductive hormone analyses	Blood testosterone increased	2	
		Thyroid analyses	Thyroxine abnormal	1	
			Thyroxine increased	1	
	Enzyme investigations NEC	Skeletal and cardiac muscle analyses	Blood creatine phosphokinase increased	2	
			Troponin increased	1	
		Tissue enzyme analyses NEC	Blood alkaline phosphatase increased	1	
	Gastrointestinal investigations	Digestive enzymes	Amylase	1	
			Amylase increased	7	
			Lipase increased	5	
			Pancreatic enzymes	2	
			Pancreatic enzymes increased	1	
		Faecal analyses NEC	Faecal calprotectin	1	
		Gastrointestinal function diagnostic procedures	Gastrointestinal stoma output increased	1	
	Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	International normalised ratio abnormal	1	
			International normalised ratio decreased	2	

			International normalised ratio fluctuation	1	
			International normalised ratio increased	2	
		Platelet analyses	Platelet count decreased	2	
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	7	
			Blood bilirubin increased	2	
			Hepatic enzyme abnormal	3	
			Hepatic enzyme decreased	1	
			Hepatic enzyme increased	5	
			Liver function test abnormal	13	
			Liver function test increased	8	
		Hepatobiliary imaging procedures	Liver scan	2	
	Immunology and allergy investigations	Immune response protein analyses NEC	Interleukin level increased	1	
	Investigations, imaging and histopathology procedures NEC	Investigations NEC	Blood test	1	
			Blood test abnormal	2	
			Quality of life decreased	1	

Lipid analyses	Cholesterol analyses	Blood cholesterol increased	3	
Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Blood bicarbonate decreased	1	
		Blood lactic acid increased	2	
		Oxygen saturation decreased	1	
	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose abnormal	4	
		Blood glucose decreased	28	
		Blood glucose fluctuation	2	
		Blood glucose increased	20	
		Glycosylated haemoglobin abnormal	3	
		Glycosylated haemoglobin decreased	9	
		Glycosylated haemoglobin increased	26	
	Haem metabolism analyses	Blood methaemoglobin	1	
	Metabolism tests NEC	Blood ketone body	6	
		Urine ketone body	1	
		Urine ketone body present	1	
	Vitamin analyses	Vitamin B12 abnormal	1	

		Vitamin B12 decreased	1	
Neurological, special senses and psychiatric investigations	Ophthalmic function diagnostic procedures	Intraocular pressure increased	1	
Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature fluctuation	2	
		Body temperature increased	3	
		Menstruation normal	1	
		Weight abnormal	1	
		Weight decreased	52	
		Weight increased	46	
Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein	1	
		Globulins increased	1	
		Protein total increased	1	
Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine abnormal	1	
		Blood creatinine increased	3	
		Glomerular filtration rate abnormal	2	
		Glomerular filtration rate decreased	6	
	Urinalysis NEC	Blood urine	1	
		Blood urine present	5	
		Nitrite urine present	1	
	Urinary tract function analyses NEC	Urine output decreased	6	

	Toxicology and therapeutic drug monitoring	Therapeutic drug monitoring analyses	Immunosuppressant drug level increased	1	
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood calcium decreased	1	
			Blood calcium increased	1	
			Blood iron decreased	5	
			Blood magnesium decreased	1	
			Blood phosphorus decreased	1	
			Serum ferritin increased	1	
		Water and electrolyte analyses NEC	Blood electrolytes abnormal	1	
	Metabolism and nutrition disorders	Metabolic acidoses (excl diabetic acidoses)	Ketoacidosis	7	
			Ketosis	6	
			Lactic acidosis	3	
			Metabolic acidosis	1	
			Starvation ketoacidosis	10	
		Metabolic alkaloses	Metabolic alkalosis	1	
		Appetite and general nutritional disorders	Appetite disorder	5	
			Decreased appetite	84	
			Food craving	14	
			Hyperphagia	1	
			Hypophagia	7	

	General nutritional disorders NEC	Increased appetite	21	
		Lack of satiety	1	
		Abnormal loss of weight	3	
		Abnormal weight gain	1	
		Feeding disorder	16	
		Food aversion	3	
		Malnutrition	3	
		Starvation	2	
		Weight loss poor	37	
	Bone, calcium, magnesium and phosphorus metabolism disorders	Calcium metabolism disorders		
		Hypercalcaemia	1	
		Hypocalcaemia	1	
		Magnesium metabolism disorders		
		Hypomagnesaemia	1	
	Diabetic complications	Phosphorus metabolism disorders		
		Hypophosphataemia	3	
		Diabetic complications NEC		
		Diabetic ketoacidosis	12	
	Electrolyte and fluid balance conditions	Diabetic ketosis	2	
		Euglycaemic diabetic ketoacidosis	7	
		Electrolyte imbalance NEC		
		Electrolyte depletion	1	
		Electrolyte imbalance	2	
		Fluid intake decreased		
		Fluid intake reduced	2	
		Fluid intake increased		
		Polydipsia	2	
	Potassium imbalance	Hyperkalaemia	1	
		Hypokalaemia	11	

	Sodium imbalance	Hyponatraemia	2	
	Total fluid volume decreased	Dehydration	67	
	Total fluid volume increased	Fluid retention	2	
Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Alcohol intolerance	3	
		Food intolerance	1	
		Gluten sensitivity	1	
		Histamine intolerance	1	
	Sugar intolerance (excl glucose intolerance)	Carbohydrate intolerance	1	
		Lactose intolerance	1	
Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Diabetes mellitus inadequate control	7	
		Type 3 diabetes mellitus	1	
	Hyperglycaemic conditions NEC	Hyperglycaemia	4	
	Hypoglycaemic conditions NEC	Hypoglycaemia	73	
		Hypoglycaemia unawareness	1	
		Postprandial hypoglycaemia	1	
		Shock hypoglycaemic	1	
	Iron deficiencies	Iron deficiency	1	
Iron and trace metal metabolism disorders				



	Metabolism disorders NEC	Metabolic disorders NEC	Hyperamylasaemia	1	
			Hyperlipasaemia	1	
			Metabolic disorder	1	
	Purine and pyrimidine metabolism disorders	Disorders of purine metabolism	Gout	9	
	Vitamin related disorders	Vitamin deficiencies NEC	Hypovitaminosis	1	
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone disorders NEC	Bone lesion	1	
		Bone related signs and symptoms	Bone pain	6	
			Pain in jaw	6	
			Spinal pain	2	
	Connective tissue disorders (excl congenital)	Lupus erythematosus (incl subtypes)	Systemic lupus erythematosus	1	
	Joint disorders	Arthropathies NEC	Arthritis	3	
			Polyarthritis	1	
		Joint related disorders NEC	Temporomandibular pain and dysfunction syndrome	1	
		Joint related signs and symptoms	Arthralgia	49	
			Joint stiffness	3	
			Joint swelling	2	
		Osteoarthropathies	Spinal osteoarthritis	1	
		Rheumatoid arthropathies	Rheumatoid arthritis	1	
		Muscle disorders	Muscle pains	Fibromyalgia	3
	Myalgia			69	
	Muscle related signs and symptoms NEC		Muscle atrophy	6	

			Muscle fatigue	3	
			Muscle mass	1	
			Muscle spasms	29	
			Muscle tightness	3	
			Muscle twitching	4	
		Muscle tone abnormalities	Muscle rigidity	1	
			Trismus	3	
		Muscle weakness conditions	Muscular weakness	7	
		Myopathies	Myopathy	1	
			Rhabdomyolysis	1	
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Mastication disorder	1	
			Mobility decreased	3	
			Musculoskeletal stiffness	7	
		Musculoskeletal and connective tissue pain and discomfort	Back pain	49	
			Flank pain	3	
			Limb discomfort	3	
			Musculoskeletal chest pain	10	
			Musculoskeletal discomfort	5	
			Musculoskeletal pain	1	
			Neck pain	22	
			Pain in extremity	39	
		Soft tissue disorders NEC	Groin pain	1	
			Neck mass	1	
	Tendon, ligament and cartilage disorders	Cartilage disorders	Costochondritis	2	
		Ligament disorders	Ligament pain	1	

		Tendon disorders	Tendonitis	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasms malignant and unspecified (incl nipple)	Breast and nipple neoplasms malignant	Breast cancer	4	
	Cutaneous neoplasms benign	Skin neoplasms benign	Seborrhoeic keratosis	1	
	Endocrine neoplasms benign	Thyroid neoplasms benign	Benign neoplasm of thyroid gland	1	
	Endocrine neoplasms malignant and unspecified	Endocrine neoplasms malignant and unspecified NEC	Neuroendocrine tumour	2	1
			Thyroid neoplasm	2	
		Thyroid neoplasms malignant	Papillary thyroid cancer	1	
			Thyroid cancer	3	
	Gastrointestinal neoplasms malignant and unspecified	Gastrointestinal neoplasms malignant NEC	Gastrointestinal carcinoma	1	
		Pancreatic neoplasms malignant (excl islet cell and carcinoid)	Pancreatic carcinoma	1	
			Pancreatic carcinoma metastatic	1	
		Salivary gland neoplasms unspecified malignancy	Salivary gland neoplasm	1	
	Hepatobiliary neoplasms malignant and unspecified	Bile duct neoplasms malignant	Cholangiocarcinoma	2	
		Hepatic neoplasms malignant	Hepatic cancer	1	

	Miscellaneous and site unspecified neoplasms malignant and unspecified	Neoplasms malignant site unspecified NEC	Neoplasm malignant	1	
		Neoplasms unspecified malignancy and site unspecified NEC	Neoplasm	1	
	Neoplasm related morbidities	Oncologic complications and emergencies	Infected neoplasm	1	
	Ocular neoplasms	Ocular neoplasms benign	Benign neoplasm of retina	1	
	Renal and urinary tract neoplasms malignant and unspecified	Renal neoplasms malignant	Renal cancer	1	
			Renal cell carcinoma	1	
	Respiratory and mediastinal neoplasms malignant and unspecified	Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	Lung neoplasm malignant	2	
	Skin neoplasms malignant and unspecified	Skin melanomas (excl ocular)	Malignant melanoma	1	
Nervous system disorders	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral thrombosis	1	
			Cerebrovascular accident	15	1
			Haemorrhage intracranial	1	
			Haemorrhagic stroke	1	
			Ruptured cerebral aneurysm	1	

	Transient cerebrovascular events	Transient ischaemic attack	5	
Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	2	
	Glossopharyngeal nerve disorders	Glossopharyngeal neuralgia	1	
	Olfactory nerve disorders	Parosmia	5	
	Optic nerve disorders NEC	Optic neuritis	4	
Headaches	Headaches NEC	Cluster headache	2	
		Cold-stimulus headache	1	
		Headache	2,562	
		Sinus headache	1	
		Tension headache	4	
	Migraine headaches	Atypical migraine	1	
		Hemiplegic migraine	2	
		Migraine	50	
		Migraine without aura	2	
		Ophthalmic migraine	2	
		Retinal migraine	1	
Increased intracranial pressure and hydrocephalus	Increased intracranial pressure disorders	Idiopathic intracranial hypertension	1	
Mental impairment disorders	Memory loss (excl dementia)	Amnesia	6	
		Memory impairment	1	
	Mental impairment (excl dementia and memory loss)	Disturbance in attention	6	

		Mental impairment	1	
Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Akathisia	1	
		Hypokinesia	1	
		Psychomotor hyperactivity	1	
	Dystonias	Dystonia	1	
	Paralysis and paresis (excl cranial nerve)	Paralysis	2	
	Parkinson's disease and parkinsonism	Freezing phenomenon	1	
	Tremor (excl congenital)	Tremor	32	
Neurological disorders NEC	Coma states	Coma	1	
		Diabetic coma	1	
		Hypoglycaemic coma	1	
	Coordination and balance disturbances	Balance disorder	5	
		Nystagmus	2	
	Cortical dysfunction NEC	Aphasia	2	
	Disturbances in consciousness NEC	Hyperglycaemic unconsciousness	1	
		Lethargy	47	
		Loss of consciousness	6	
		Sedation	1	
		Somnolence	22	
		Syncope	24	
	Neurological signs and symptoms NEC	Brain fog	9	
		Dizziness	245	
		Dizziness exertional	1	
		Dizziness postural	10	

			Head discomfort	4	
			Myoclonus	1	
			Presyncope	7	
		Paraesthesias and dysaesthesias	Burning sensation	10	
			Dysaesthesia	3	
			Hyperaesthesia	7	
			Hypoaesthesia	20	
			Paraesthesia	50	
		Sensory abnormalities NEC	Ageusia	8	
			Allodynia	40	
			Aura	1	
			Dysgeusia	49	
			Neuralgia	13	
			Restless legs syndrome	8	
			Sensory disturbance	2	
			Sensory loss	2	
			Taste disorder	18	
		Speech and language abnormalities	Dysarthria	2	
			Incoherent	1	
			Speech disorder	2	
	Neuromuscular disorders	Autonomic nervous system disorders	Diabetic autonomic neuropathy	1	
	Peripheral neuropathies	Mononeuropathies	Meralgia paraesthetica	1	
			Nerve compression	1	
			Peroneal nerve palsy	1	
			Peripheral neuropathies NEC	1	

			Neuropathy peripheral	8	
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Epilepsy	1	
			Hypoglycaemic seizure	3	
			Seizure	19	
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	3	
		Sleep disturbances NEC	Sleep deficit	1	
	Spinal cord and nerve root disorders	Lumbar spinal cord and nerve root disorders	Sciatica	1	
	Structural brain disorders	Structural brain disorders NEC	Brain injury	2	2
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions spontaneous	Abortion spontaneous	5	
	Maternal complications of pregnancy	Maternal complications of pregnancy NEC	Biochemical pregnancy	1	
			Morning sickness	4	
	Pregnancy, labour, delivery and postpartum conditions	High risk pregnancies	High risk pregnancy	1	
		Normal pregnancy, labour and delivery	Pregnancy	9	
		Unintended pregnancies	Pregnancy with implant contraceptive	1	
			Unwanted pregnancy	1	
Product issues	Device issues	Device issues NEC	Device delivery system issue	6	
			Device failure	2	



			Device malfunction events NEC	Device issue	3	
				Device leakage	2	
				Device malfunction	5	
			Device physical property and chemical issues	Device breakage	1	
				Device defective	9	
				Device mechanical issue	6	
				Device physical property issue	1	
			Counterfeit, falsified and substandard products	Product counterfeit	2	
				Suspected counterfeit product	25	
			Product label issues	Physical product label issue	1	
				Product label on wrong product	1	
			Product packaging issues	Product packaging quantity issue	2	
			Product physical issues	Liquid product physical issue	4	
				Product after taste	1	
				Product leakage	2	
				Product odour abnormal	2	
				Product physical consistency issue	1	

			Product taste abnormal	1	
			Product quality issues NEC	Drug delivery system issue	1
				Product delivery mechanism issue	1
				Product quality issue	1
				Product substitution issue	2
		Product supply and availability issues	Product availability issue	4	
	Psychiatric disorders	Adjustment disorders (incl subtypes)	Adjustment disorders	Adjustment disorder with depressed mood	1
	Anxiety disorders and symptoms	Anxiety disorders and symptoms	Anxiety disorders NEC	Anxiety disorder	2
			Anxiety symptoms	Agitation	4
				Anxiety	138
				Nervousness	7
				Stress	5
				Tension	1
			Fear symptoms and phobic disorders (incl social phobia)	Fear	1
				Fear of death	1
			Obsessive-compulsive disorders and symptoms	Dermatillomania	1
		Panic attacks and disorders	Panic attack	35	
			Panic disorder	3	
			Panic reaction	4	

Changes in physical activity	Increased physical activity levels	Restlessness	3	
	Stereotypies and automatisms	Bruxism	1	
		Posturing	1	
Cognitive and attention disorders and disturbances	Cognitive and attention disorders and disturbances NEC	Mental fatigue	2	
	Learning disorders	Learning disorder	1	
Communication disorders and disturbances	Communications disorders	Communication disorder	1	
Deliria (incl confusion)	Confusion and disorientation	Confusional state	13	
		Disorientation	3	
	Deliria	Delirium	1	
Depressed mood disorders and disturbances	Depressive disorders	Depression	83	
		Depression suicidal	12	
		Major depression	2	
	Mood alterations with depressive symptoms	Anhedonia	4	
		Decreased interest	2	
		Depressed mood	347	
		Feeling of despair	1	
		Negative thoughts	3	
		Tearfulness	2	
Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	5	
		Hallucination, auditory	1	
	Perception disturbances NEC	Flashback	1	
		Illusion	1	

		Near death experience	1	
		Thinking disturbances	Derailment	1
			Intrusive thoughts	5
			Tachyphrenia	3
Eating disorders and disturbances	Eating disorders NEC	Binge eating	2	
		Eating disorder	1	
Manic and bipolar mood disorders and disturbances	Mood alterations with manic symptoms	Hypomania	1	
		Mania	2	
Mood disorders and disturbances NEC	Affect alterations NEC	Affect lability	1	
	Emotional and mood disturbances NEC	Anger	4	
		Emotional distress	4	
		Emotional poverty	3	
		Euphoric mood	1	
		Frustration tolerance decreased	1	
		Irritability	13	
		Mood altered	10	
	Fluctuating mood symptoms	Mood swings	7	
	Mood disorders NEC	Affective disorder	1	
		Apathy	2	
Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Paranoia	2	
		Personality change	3	
		Social avoidant behaviour	2	
	Personality disorders NEC	Personality disorder	2	
		Self esteem decreased	1	

Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	3	
	Psychiatric symptoms NEC	Psychiatric symptom	2	
Psychiatric disorders NEC	Mental disorders due to a general medical condition NEC	Neuropsychiatric syndrome	1	
	Mental disorders NEC	Mental disorder	6	
	Substance related and addictive disorders	Alcoholism	2	
Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Acute psychosis	1	
		Psychotic disorder	1	
Sexual dysfunctions, disturbances and gender identity disorders	Orgasmic disorders and disturbances	Female orgasmic disorder	1	
	Sexual desire disorders	Libido decreased	6	
		Libido disorder	1	
		Libido increased	1	
		Loss of libido	4	
Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	67	
		Terminal insomnia	1	
	Dyssomnias	Poor quality sleep	10	
	Parasomnias	Abnormal dreams	18	
		Nightmare	16	
		Sleep sex	1	
		Sleep talking	1	

		Sleep disorders NEC	Sleep disorder	9	
			Sleep disorder due to a general medical condition	2	
			Sleep disorder due to general medical condition, insomnia type	6	
	Somatic symptom and related disorders	Somatic symptom disorders	Somatic symptom disorder	1	
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour	Completed suicide	2	2
			Intentional self-injury	2	
			Self-injurious ideation	2	
			Suicidal behaviour	5	
			Suicidal ideation	63	
			Suicide attempt	5	
			Suicide threat	3	
Renal and urinary disorders	Bladder and bladder neck disorders (excl calculi)	Bladder infections and inflammations	Cystitis interstitial	2	
	Nephropathies	Nephritis NEC	Tubulointerstitial nephritis	1	
	Renal disorders (excl nephropathies)	Renal disorders NEC	Renal disorder	2	
		Renal failure and impairment	Acute kidney injury	18	
			Anuria	1	

			Oliguria	1	
			Renal failure	4	
			Renal impairment	10	
			Renal injury	1	
		Renal obstructive disorders	Hydronephrosis	1	
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Bladder discomfort	1	
			Bladder pain	2	
			Dysuria	3	
			Incontinence	3	
			Micturition urgency	2	
			Pollakiuria	9	
			Urinary hesitation	1	
			Urinary incontinence	1	
			Urinary retention	6	
			Urinary straining	1	
		Urinary abnormalities	Chromaturia	9	
			Haematuria	7	
			Urine odour abnormal	3	
		Urinary tract signs and symptoms NEC	Haemorrhage urinary tract	2	
			Nocturia	1	
			Polyuria	5	
			Renal colic	2	
			Renal pain	11	
	Urolithiasis	Renal lithiasis	Nephrolithiasis	14	1
Reproductive system and breast disorders	Breast disorders	Breast disorders NEC	Breast enlargement	1	
		Breast signs and symptoms	Breast pain	3	
			Breast tenderness	2	
		Lactation disorders	Lactation disorder	1	

Menopause related conditions	Menopausal effects NEC	Menopausal symptoms	1	
	Menopausal effects on the genitourinary tract	Postmenopausal haemorrhage	7	
Menstrual cycle and uterine bleeding disorders	Menstruation and uterine bleeding NEC	Abnormal menstrual clots	2	
		Dysmenorrhoea	13	
		Intermenstrual bleeding	29	
		Menstrual clots	3	
		Menstrual disorder	27	
		Menstruation irregular	38	
		Ovulation pain	1	
		Unexpected vaginal bleeding on hormonal IUD	1	
		Withdrawal bleed	1	
	Menstruation with decreased bleeding	Amenorrhoea	5	
		Hypomenorrhoea	2	
		Menstruation delayed	38	
		Oligomenorrhoea	2	
	Menstruation with increased bleeding	Heavy menstrual bleeding	54	
		Polymenorrhoea	8	
Ovarian and fallopian tube disorders	Ovarian and fallopian tube cysts and neoplasms	Ovarian cyst ruptured	1	
		Polycystic ovaries	1	



	Reproductive tract disorders NEC	Reproductive tract disorders NEC (excl neoplasms)	Genital haemorrhage	1		
		Reproductive tract signs and symptoms NEC	Pruritus genital	3		
	Sexual function and fertility disorders	Erection and ejaculation conditions and disorders	Ejaculation disorder	1		
			Erectile dysfunction	3		
		Sexual function and fertility disorders NEC	Infertility	1		
			Sexual dysfunction	1		
	Uterine, pelvic and broad ligament disorders	Pelvis and broad ligament disorders NEC	Pelvic haemorrhage	1		
		Uterine tone disorders	Uterine spasm	2		
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vaginal haemorrhage	46		
			Vulval haemorrhage	2		
		Vulvovaginal signs and symptoms	Vaginal discharge	2		
			Vaginal lesion	1		
			Vulvovaginal dryness	2		
	Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	6	
				Wheezing	3	
Lower respiratory tract disorders (excl obstruction and infection)		Lower respiratory tract inflammatory and immunologic conditions	Diffuse alveolar damage	1		
			Pneumonitis	1		
		Parenchymal lung disorders NEC	Acute interstitial pneumonitis	1		

Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	16	
Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	35	
		Hypopnoea	2	
		Respiration abnormal	1	
	Coughing and associated symptoms	Cough	15	
		Haemoptysis	2	
		Productive cough	1	
		Sputum discoloured	1	
	Respiratory tract disorders NEC	Aspiration	1	
Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Hiccups	15	
	Upper respiratory tract signs and symptoms	Aphonia	2	
		Catarrh	1	
		Dry throat	1	
		Dysphonia	15	
		Oropharyngeal discomfort	1	
		Oropharyngeal pain	12	
		Rhinalgia	1	
		Rhinorrhoea	3	
		Sinus pain	1	
		Sneezing	1	
		Throat irritation	7	
		Throat tightness	1	
		Upper-airway cough syndrome	2	

	Thoracic disorders (excl lung and pleura)	Mediastinal disorders	Pneumomediastinum	1	
	Upper respiratory tract disorders (excl infections)	Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	Reflux laryngitis	3	
		Nasal congestion and inflammations	Nasal congestion	2	
		Nasal disorders NEC	Epistaxis	16	
		Pharyngeal disorders (excl infections and neoplasms)	Oropharyngeal spasm	1	
			Pharyngeal swelling	5	
			Tonsillar hypertrophy	1	
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	14	
		Urticarias	Idiopathic urticaria	1	
			Urticaria	62	
	Cornification and dystrophic skin disorders	Hyperkeratoses	Hyperkeratosis	1	
		Skin hyperplasias and hypertrophies	Skin hypertrophy	1	
		Skin hypoplasias and atrophies	Skin striae	1	
		Skin preneoplastic conditions NEC	Actinic cheilitis	1	

Cutaneous neoplasms benign	Skin cysts and polyps	Dermal cyst	1	
Epidermal and dermal conditions	Bullous conditions	Blister	5	
		Dermatitis bullous	2	
		Dermatitis herpetiformis	1	
	Dermal and epidermal conditions NEC	Dry skin	12	
		Pain of skin	22	
		Papule	1	
		Sensitive skin	44	
		Skin burning sensation	9	
		Skin discolouration	1	
		Skin disorder	1	
		Skin induration	1	
		Skin lesion	2	
		Skin reaction	8	
		Skin sensitisation	14	
		Skin swelling	3	
	Dermatitis and eczema	Dermatitis	1	
		Dermatitis allergic	10	
		Dermatitis atopic	1	
		Dermatitis contact	1	
		Eczema	5	
		Intertrigo	2	
		Skin irritation	8	
	Dermatitis ascribed to specific agent	Drug eruption	2	

	Drug reaction with eosinophilia and systemic symptoms	2	
	Severe cutaneous adverse reaction	1	
Erythemas	Erythema	27	
Exfoliative conditions	Skin exfoliation	3	
Granulomatous and deep cutaneous inflammatory conditions	Cutaneous sarcoidosis	1	
Papulosquamous conditions	Lichen planus	1	
	Pityriasis rosea	1	
Photosensitivity and photodermatosis conditions	Photosensitivity reaction	3	
Pruritus NEC	Pruritus	91	
Psoriatic conditions	Psoriasis	2	
Rashes, eruptions and exanthems NEC	Mucocutaneous rash	1	
	Rash	119	
	Rash erythematous	28	
	Rash macular	7	
	Rash maculo-papular	2	
	Rash papular	4	
	Rash pruritic	21	
	Rash vesicular	2	

	Pigmentation disorders	Hyperpigmentation disorders	Chloasma	1	
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Cellulite	1	
			Cutaneous symptom	6	
			Skin mass	2	
		Skin and subcutaneous tissue ulcerations	Skin ulcer	1	
	Skin appendage conditions	Acnes	Acne	11	
		Alopecias	Alopecia	139	
		Apocrine and eccrine gland disorders	Cold sweat	8	
			Hidradenitis	1	
			Hyperhidrosis	43	
			Miliaria	1	
			Night sweats	4	
		Pilar disorders NEC	Hair colour changes	1	
			Hair growth abnormal	1	
			Hair texture abnormal	1	
		Rosaceas	Rosacea	1	
	Skin vascular abnormalities	Purpura and related conditions	Purpura	2	
			Purpura senile	1	
Social circumstances	Age related factors	Age related issues	Menopause	2	
	Economic and housing issues	Economic circumstances	Low income	1	
		Employment issues	Stress at work	1	
	Family issues	Family and partner issues	Anxious parent	1	
	Legal issues	Criminal activity	Drug diversion	1	
	Lifestyle issues	Alcohol product use	Alcohol use	3	
		Disability issues	Bedridden	1	

Surgical and medical procedures			Impaired work ability	1	
			Social issues NEC	Gambling	1
			Tobacco use	Ex-tobacco user	1
				Non-tobacco user	1
	Bone and joint therapeutic procedures	Joint therapeutic procedures	Knee arthroplasty	1	
			Knee operation	1	
	Endocrine gland therapeutic procedures	Hormonal therapeutic procedures NEC	Hormone replacement therapy	1	
			Thyroid therapeutic procedures	Thyroid therapy	1
	Gastrointestinal therapeutic procedures	Gastrointestinal therapeutic procedures NEC	Prophylaxis of nausea and vomiting	1	
			Large intestine therapeutic procedures	Appendectomy	4
	Hepatobiliary therapeutic procedures	Biliary tract and gallbladder therapeutic procedures	Cholecystectomy	10	
	Nervous system, skull and spine therapeutic procedures	Skull and brain therapeutic procedures	Brain operation	1	
	Obstetric and gynaecological therapeutic procedures	Contraceptive methods female	Contraception	1	
		Induced abortions	Abortion induced	1	
		Uterine therapeutic procedures	Hysterectomy	1	
			Myomectomy	1	

	Therapeutic procedures and supportive care NEC	Anaesthesia and allied procedures	Local anaesthesia	1	
		Therapeutic procedures NEC	Drug titration	2	
			Hospitalisation	19	
			Rest regimen	1	
			Surgery	2	
			Therapy interrupted	1	
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	10	
			Raynaud's phenomenon	2	
	Decreased and nonspecific blood pressure disorders and shock	Blood pressure disorders NEC	Blood pressure fluctuation	1	
		Circulatory collapse and shock	Circulatory collapse	6	1
			Shock	3	
		Vascular hypotensive disorders	Hypotension	27	
			Orthostatic hypotension	3	
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Thrombosis	3	
		Peripheral embolism and thrombosis	Deep vein thrombosis	11	
			Thrombophlebitis	1	
	Vascular disorders NEC	Non-site specific vascular disorders NEC	Hyperaemia	1	
			Vascular calcification	1	
		Peripheral vascular disorders NEC	Cyanosis	2	
			Flushing	7	
			Hot flush	12	
		Site specific vascular disorders NEC	Pallor	5	



Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	7	
Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	18	
Vascular infections and inflammations	Phlebitis NEC	Phlebitis	1	
	Vasculitides NEC	Vasculitis	2	
Venous varices	Varicose veins NEC	Varicose vein	2	
Total Reports			20,022	
Total Reactions			31,620	
Total Fatal Reports				18