COVID-19 mRNA Pfizer-BioNTech Vaccine Analysis Print

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All UK spontaneous reports received between 09/12/20 and 10/11/21 for mRNA Pfizer/BioNTech vaccine.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	3	C
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Anaemias NEC		
Anaemia	107	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
Anaemias haemolytic NEC		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	6	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	14	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
Anaemias haemolytic mechanical factor	1	
Microangiopathic haemolytic anaemia	1	0
Bleeding tendencies	1	U
	1	0
Haemorrhagic diathesis	1	0
Increased tendency to bruise	45	0
Spontaneous haematoma	2	0
Coagulation factor deficiencies		
Acquired haemophilia	2	0
Coagulopathies		-
Abnormal clotting factor	4	0
Antiphospholipid syndrome	5	0
Coagulopathy	24	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
Eosinophilic disorders		
Eosinophilia	12	0
Haematological disorders		
Blood disorder	3	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	7	0
Methaemoglobinaemia	1	0
Haemolyses NEC		
Haemolysis	6	0
Intravascular haemolysis	1	0
Leukocytoses NEC		
Leukocytosis	1	0
Lymphocytosis	6	C
	10	
Neutrophilia	10	C
Leukopenias NEC		
Leukopenia	4	1
Lymphopenia	4	C
Lymphatic system disorders NEC		

Reaction Name Blood disorders cont'd	Total	Fatal
Blood disorders Blood disorders cont'd Abdominal lymphadenopathy	3	(
Hilar lymphadenopathy	3	(
Lymph node pain	1619	
Lymph node ulcer	1019	(
Lymphadenitis	138	
	10161	(
Lymphadenopathy Lymphatic disorder	10101	
Lymphatic disorder	1	(
Necrotic lymphadenopathy	3	
	11	
Pseudolymphoma		(
Retroperitoneal lymphadenopathy	1	Ĺ
Marrow depression and hypoplastic anaemias	2	
Aplasia pure red cell	2	(
Hypoplastic anaemia Mualaguppragaian	2	(
Myelosuppression	7	
Pancytopenia		C
	0	· · · · ·
Autoimmune neutropenia	2	(
Neutropenia	37	L L
Platelet disorders NEC	1	0
Platelet anisocytosis Platelet disorder		(
	4	C
Polycythaemia (excl rubra vera)	2	· · · · ·
Polycythaemia	3	C
Purpuras (excl thrombocytopenic)	1	
Purpura non-thrombocytopenic	1	C
Red blood cell abnormal findings NEC	1	
Macrocytosis		(
Polychromasia	2	(
Red blood cell abnormality	2	C
Spleen disorders	1	· · · · ·
Spleen atrophy		(
Splenic infarction	2	(
Splenic thrombosis	1	(
Splenic vein thrombosis	1	
Splenomegaly	11	(
Thrombocytopenias		
Acquired amegakaryocytic thrombocytopenia	1	(
Immune thrombocytopenia	73	
Thrombocytopenia	204	
Thrombocytopenic purpura	6	
Thrombotic thrombocytopenic purpura	6	(
Thrombocytoses		-
Thrombocytosis	6	(
Blood disorders SOC TOTAL	12617	3

Reaction Name	Total	Fatal
Cardiac disorders		
Aortic valvular disorders		
Aortic valve incompetence	1	0
Cardiac conduction disorders		
Atrioventricular block	15	1
Atrioventricular block complete	2	1
Atrioventricular block first degree	1	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	2	0
Bundle branch block right	1	0
Cardiac disorders NEC		
Acute cardiac event	3	0
Cardiac disorder	55	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	5	0
Intracardiac thrombus	6	0
Cardiac hypertensive complications		
Hypertensive heart disease	1	0
Cardiac infections and inflammations NEC		
Carditis	2	0
Cardiac neoplasms NEC		
Pericardial cyst	1	0
Cardiac signs and symptoms NEC		
Cardiac discomfort	19	0
Cardiovascular symptom	1	0
Palpitations	3355	1
Cardiac valve disorders NEC		
Cardiac valve disease	2	0
Heart valve incompetence	2	0
Cardiomyopathies		
Cardiomyopathy	5	0
Congestive cardiomyopathy	6	0
Stress cardiomyopathy	2	0
Coronary artery disorders NEC		
Coronary artery disease	6	3
Coronary artery occlusion	2	0
Coronary artery thrombosis	2	1
Endocarditis NEC		
Endocarditis noninfective	1	1
Heart failures NEC		
Cardiac failure	68	8
Cardiac failure acute	5	1
Cardiac failure chronic	2	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
Ischaemic coronary artery disorders		
Acute coronary syndrome	3	0
Acute myocardial infarction	21	1
Angina pectoris	187	1
Angina pectors Angina unstable	2	0
Arteriospasm coronary	3	0

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Microvascular coronary artery disease	2	C
Myocardial infarction	200	34
Myocardial ischaemia	9	4
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	6	C
Mitral valve prolapse	1	C
Myocardial disorders NEC		
Cardiac amyloidosis	1	C
Cardiac aneurysm	1	1
Cardiomegaly	29	2
Left atrial dilatation	1	C
Left ventricular dysfunction	9	C
Left ventricular enlargement	1	0
Left ventricular hypertrophy	2	C
Myocardial fibrosis	4	C
Myocardial haemorrhage	1	C
Myocardial injury	10	C
Myocardial oedema	4	C
Myocardial rupture	1	C
Right ventricular enlargement	1	C
Ventricular hypertrophy	1	C
Noninfectious myocarditis		
Myocarditis	413	1
Noninfectious pericarditis		
Pericarditis	320	1
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	34	1
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	C
Rate and rhythm disorders NEC		
Arrhythmia	124	
Bradycardia	60	C
Bradycardia foetal	2	1
Cardiac flutter	401	
Extrasystoles	145	
Heart alternation	1	(
Paroxysmal arrhythmia	1	(
Postural orthostatic tachycardia syndrome	19	(
Tachyarrhythmia	4	(
Tachycardia	890	(
Tachycardia foetal	1	(
Tachycardia paroxysmal	1	(
Right ventricular failures		
Čor pulmonale	1	
Supraventricular arrhythmias		
Arrhythmia supraventricular	11	(
Atrial fibrillation	189	
Atrial flutter	26	

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Atrial tachycardia	9	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	5	0
Sinus bradycardia	11	0
Sinus node dysfunction	1	0
Sinus tachycardia	53	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	37	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	4	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	98	39
Cardio-respiratory arrest	1	1
Pulseless electrical activity	4	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	23	0
Ventricular fibrillation	6	1
Ventricular tachycardia	12	0
Cardiac disorders SOC TOTAL	7020	115

Reaction Name	Total	Fatal
Congenital disorders		
Autosomal chromosomal abnormalities	_	
Trisomy 8	1	
Cardiac disorders congenital NEC		
Heart disease congenital	12	
Cardiac hypoplasias congenital		
Ventricular hypoplasia	1	
Cardiac septal defects congenital		
Atrial septal defect	2	
Hypertrophic cardiomyopathy	1	
Ventricular septal defect	1	
Cardiac valve disorders congenital		
Bicuspid aortic valve	2	
Central nervous system disorders congenital NEC		
Spina bifida	1	
Syringomyelia	1	
Cerebellar disorders congenital		
Arnold-Chiari malformation	1	
Hereditary ataxia	1	
Cerebral disorders congenital		
Anencephaly	2	
Cerebral palsy	3	
Coagulation disorders congenital		
Haemophilia	2	
Congenital disorders NEC		
Foetal malformation	1	
Heterotaxia	1	
Young's syndrome	1	
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	2	
Gastrointestinal tract disorders congenital NEC		
Gastroschisis	2	
Great vessel disorders congenital	2	
Congenital great vessel anomaly	1	
Transposition of the great vessels	1	
Haematological disorders congenital NEC		
• •	1	
Amegakaryocytic thrombocytopenia	1	
Neonatal alloimmune thrombocytopenia		
Haemoglobinopathies congenital Congenital methaemoglobinaemia	1	
Inborn errors of lipid metabolism	1	
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	
Inborn errors of metabolism NEC	1	
Alpha-1 antitrypsin deficiency		
Inborn errors of porphyrin metabolism		
Porphyria	l l	
Lymphatic system disorders congenital		
Cystic lymphangioma	3	
Male reproductive tract disorders congenital		
Cryptorchism	1	
Micropenis	3	
Phimosis	1	
Musculoskeletal and connective tissue disorders of limbs congenital		
Developmental hip dysplasia	1	

Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Musculoskeletal and connective tissue disorders of spine congenital		
Block vertebra	1	0
Brachyolmia	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	78	0

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear canal erythema	1	0
Ear congestion	29	0
Ear discomfort	92	0
Ear disorder	16	0
Ear haemorrhage	9	0
Ear pain	910	0
Ear pruritus	9	0
Ear swelling	33	0
Otorrhoea	4	0
Eustachian tube disorders		-
Eustachian tube disorder	4	0
Eustachian tube dysfunction	8	0
Eustachian tube obstruction	4	0
External ear disorders NEC		-
Auricular swelling	2	0
Excessive cerumen production	8	0
External ear pain	2	0
Red ear syndrome	2	0
External ear infections and inflammations		
External ear inflammation	2	0
Hearing disorders NEC		
Auditory disorder	6	0
Diplacusis	2	0
Hearing losses		
Conductive deafness	1	0
Deafness	226	0
Deafness bilateral	8	0
Deafness neurosensory	17	0
Deafness transitory	6	0
Deafness unilateral	31	0
Hypoacusis	169	0
Sudden hearing loss	45	0
Hyperacusia		
Hyperacusis	52	0
Misophonia	3	0
Inner ear disorders NEC		
Acute vestibular syndrome	2	0
Inner ear disorder	12	0
Meniere's disease	11	0
Vestibular disorder	10	0
Inner ear infections and inflammations		
Inner ear inflammation	8	0
Inner ear signs and symptoms		
Motion sickness	57	0
Tinnitus	1832	
Vertigo	1318	
Vertigo labyrinthine	10	0
Vertigo positional	72	0
Mastoid disorders		
Mastoid effusion	1	C
Middle ear disorders NEC		
Middle ear disorder	3	C

Reaction Name	e	_	Total	Fatal
Ear disorders	Ear disorders cont'd			
Middle ear eff	usion		1	0
Middle ear infec	tions and inflammations			
Middle ear infl	ammation		1	0
Tympanic memi	brane disorders (excl infections)			
Tympanic mer	mbrane perforation		3	0
Ear disorders SO			5042	0

Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	2	0
Thyroiditis	18	0
Thyroiditis acute	3	0
Thyroiditis subacute	3	0
Adrenal cortical hypofunctions		
Addison's disease	2	0
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	13	0
Adrenal gland disorders NEC		
Adrenal haemorrhage	2	0
Anterior pituitary hyperfunction		
Pituitary-dependent Cushing's syndrome	1	0
Anterior pituitary hypofunction		
Hypopituitarism	1	0
Endocrine abnormalities of gonadal function NEC		
Oestrogen deficiency	1	0
Endocrine abnormalities of puberty		
Delayed menarche	4	0
Premature menarche	17	0
Female gonadal function disorders		
Anovulatory cycle	46	0
Ovulation delayed	32	0
Male gonadal function disorders		
Androgen deficiency	1	0
Thyroid disorders NEC		
Autoimmune thyroid disorder	1	0
Goitre	12	0
Thyroid disorder	7	0
Thyroid mass	1	0
Thyroid pain	8	0
Thyroid hyperfunction disorders		
Basedow's disease	9	0
Hyperthyroidism	35	0
Thyrotoxic crisis	3	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	1	0
Hypothyroidism	30	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	257	0

Reaction Name	Total	Fatal
Eye disorders		
Amblyopic vision impairment		
Amblyopia	6	(
Cataract conditions		(
Cataract	11	(
Choroid and vitreous haemorrhages and vascular disorders	4	<i>.</i>
Choroidal haemorrhage		(
Choroidal neovascularisation	1	C
Vitreous haemorrhage	3	C
Choroid and vitreous structural change, deposit and degeneration	-	-
	5	(
Vitreous detachment	17	(
Vitreous floaters	89	C
Colour blindness (incl acquired)		
Dyschromatopsia	9	C
Conjunctival and corneal bleeding and vascular disorders		-
Conjunctival haemorrhage	41	C
Conjunctival infections, irritations and inflammations		-
Conjunctival hyperaemia	2	C
Conjunctival irritation	1	C
Conjunctival oedema	3	C
Conjunctivitis allergic	1	C
Corneal infections, oedemas and inflammations		-
Corneal oedema	2	C
Keratitis	6	0
Ulcerative keratitis	5	C
Eyelid movement disorders		-
Blepharospasm	138	0
Excessive eye blinking	5	C
Eyelid function disorder	3	C
Eyelid myokymia	4	C
Eyelid ptosis	43	C
Paralytic lagophthalmos	2	C
Glaucomas (excl congenital)		-
Angle closure glaucoma	2	C
Glaucoma	6	C
Iris and ciliary body structural change, deposit and degeneration		
Eye colour change	3	C
Iris and uveal tract infections, irritations and inflammations		
Autoimmune uveitis	1	C
Iridocyclitis	14	C
Iritis	10	C
Uveitis	45	C
Lacrimation disorders		
Dry eye	140	(
Lacrimation increased	125	(
Lid bleeding and vascular disorders		
Eyelid bleeding	1	(
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	14	(
Chalazion	7	(
Eczema eyelids	8	(
Erythema of eyelid	9	(
Eyelid cyst	4	(

Reaction Name Eve disorders Eye disorders cont'd	Total	Fatal
Eyelid irritation	2	
Eyelid margin crusting	4	
Eyelid oedema	5	0
Eyelid rash	16	
Swelling of eyelid	116	
Swollen tear duct	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	1	0
Dermatochalasis	1	0
Eyelash changes	1	
Eyelid exfoliation	3	0
Eyelid skin dryness	2	
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lagophthalmos	3	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	27	0
Ocular vascular disorder	2	
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC	-	
Dark circles under eyes	7	0
Eye disorder	32	0
Eye oedema	16	
Eye pain	1001	0
Eye swelling	485	
Eye symptom	9	0
Eye ulcer	4	0
Eyelid disorder	12	0
Eyelid pain	12	0
Eyelids pruritus	6	0
Ocular discomfort	25	
Periorbital oedema	18	
Periorbital pain	1	0
Periorbital swelling	114	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	13	
Eye discharge	25	0
Eye inflammation	27	0
Eye irritation	84	0
Eye pruritus	222	C
Limbal swelling	3	
Ocular hyperaemia	208	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	(
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0
Eye movement disorder	32	0
Gaze palsy	1	(
Ocular myasthenia	1	

Reaction Name Eye disorders Eye disorders cont'd	Total	Fatal
	4	0
Ophthalmoplegia Strabismus	4	0
	5	0
Ocular sensation disorders	10	0
Abnormal sensation in eye	19	0
Asthenopia	141	0
Eye paraesthesia	2	0
Eyelid sensory disorder	1	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	15	0
Photophobia	435	0
Optic disc abnormalities NEC		
Papilloedema	6	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	2	0
Pupils unequal	12	0
Refractive and accommodative disorders	12	Ū
Accommodation disorder	1	0
Altered visual depth perception	3	0
Astigmatism	2	0
-	2	
Hypermetropia	1	0
Myopia Refined blooding and vessular disorders (aval refines thu)	1	U
Retinal bleeding and vascular disorders (excl retinopathy)	10	0
Retinal artery occlusion	10	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	7	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	32	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	4	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	2	0
Retinal degeneration	1	0
Retinal detachment	4	0
Retinal tear	2	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	2	0
Cystoid macular oedema	1	0
Macular oedema	4	C
Retinal vasculitis	3	C
Retinopathies NEC	3	L L

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Acute macular neuroretinopathy	1	0
Retinal exudates	2	0
Retinopathy	2	0
Scleral infections, irritations and inflammations		
Episcleritis	7	0
Scleritis	3	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	1	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	2	0
Erythropsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	2	0
Diplopia	148	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	18	0
Oscillopsia	3	0
Photopsia	122	0
Scintillating scotoma	4	0
Vision blurred	1126	0
Visual brightness	3	0
Visual snow syndrome	7	0
Visual field disorders		
Visual field defect	28	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	118	0
Blindness cortical	1	0
Blindness transient	12	0
Blindness unilateral	12	0
Central vision loss	3	0
Sudden visual loss	3	0
Visual acuity reduced	23	0
Visual acuity reduced transiently	1	C
Visual impairment	340	C
Visual pathway disorders		
Optic nerve disorder	1	C
Eve disorders SOC TOTAL	6139	

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal findings abnormal		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	16	0
Abdominal hernias NEC		
Abdominal hernia	2	0
Abdominal wall conditions NEC		
Abdominal wall haematoma	1	0
Acute and chronic pancreatitis		
Alcoholic pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	14	0
Pancreatitis acute	13	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	1	0
Anal and rectal disorders NEC		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
Anal and rectal pains		
Proctalgia	11	0
Anal and rectal signs and symptoms		Ŭ
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	4	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
Benign oral cavity neoplasms	1	0
Mouth cyst	6	0
Tongue cyst	4	0
Colitis (excl infective)		U
Autoimmune colitis	2	C
Colitis	42	1
Colitis ischaemic	42	
	1	0
Colitis microscopic	66	0
Colitis ulcerative		
Crohn's disease	40	0
Eosinophilic colitis	5	0
Inflammatory bowel disease	5	C
Dental and periodontal infections and inflammations		<u> </u>
Dental caries	1	C
Dental disorders NEC		-
Loose tooth	1	(
Malpositioned teeth	3	C
Periodontal disease	1	C
Teeth brittle	2	(
Teething	6	(
Tooth disorder	2	(
Tooth socket haemorrhage	1	(
Dental pain and sensation disorders		
Dental discomfort	6	(
Dental paraesthesia	10	(
Hyperaesthesia teeth	34	(

Reaction Name Gastrointestinal disorders Gastrointestinal disorders cont'd	Total	Fatal
Toothache	148	
Dental surface disorders	140	
Tooth discolouration	9	
	9	
Diaphragmatic hernias	G	
Hiatus hernia	6	
Diarrhoea (excl infective)	4011	
Diarrhoea	4911	
Diarrhoea haemorrhagic	21	
Diverticula		
Diverticulum Diverticulum intenting	4	
Diverticulum intestinal		
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	1	
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	
Duodenal ulcer perforation	3	
Dyspeptic signs and symptoms	100	
Dyspepsia Eximation linear fact	400	
Epigastric discomfort	14	
Eructation	45	
Faecal abnormalities NEC	10	
Abnormal faeces	19	
Faecaloma	4	
Faeces discoloured	56	
Faeces hard	2	
Faeces pale	3	
Faeces soft	10	
Mucous stools	10	
Flatulence, bloating and distension	407	
Abdominal distension	487	
Aerophagia	3	
Flatulence	170	
Gastric and oesophageal haemorrhages	_	
Gastric haemorrhage	5	
Mallory-Weiss syndrome	1	
Oesophageal varices haemorrhage	1	
Gastric ulcers and perforation		
Gastric ulcer	6	
Gastritis (excl infective)		
Chronic gastritis	3	
Gastritis	52	
Reflux gastritis	5	
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	2	
Abdominal pain	1340	
Abdominal pain lower	122	
Abdominal pain upper	2207	
Abdominal rigidity	22	
Abdominal tenderness	12	
Gastrointestinal pain	123	
Oesophageal pain	10	
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	238	

Reaction Name	Total	Fatal
	stinal disorders cont'd	
Duodenogastric reflux	4	C
Gastric dilatation	7	C
Gastrooesophageal reflux disease		
Impaired gastric emptying	9	
Infrequent bowel movements	3	C
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	C
Gastrointestinal disorders NEC		
Appendix disorder	1	0
Food poisoning	7	0
Functional gastrointestinal disorde		
Gastric disorder	9	-
Gastrointestinal disorder	21	0
Stomach mass	4	C
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	6	
Change of bowel habit	6	
Dyschezia	2	
Gastrointestinal motility disorder	3	C
Oesophageal achalasia	1	C
Gastrointestinal fistulae		
Diverticular fistula	2	C
Gastrointestinal inflammatory disord	ers NEC	
Duodenitis	1	C
Enteritis	6	
Epiploic appendagitis	2	
Gastrointestinal inflammation	3	C
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	C
Gastrointestinal mucosal dystrophie	s and secretion disorders	
Hyperchlorhydria	4	(
Gastrointestinal signs and symptom		
Abdominal discomfort	565	
Abdominal symptom	1	C
Acute abdomen	5	0
Anal incontinence	19	
Breath odour	18	
Dysphagia	193	1
Gastrointestinal wall thickening	1	0
Odynophagia	33	0
Gastrointestinal spastic and hyperm	otility disorders	
Cardiospasm	1	0
Defaecation urgency	10	
Frequent bowel movements	26	(
Gastrointestinal hypermotility	1	(
Irritable bowel syndrome	80	(
Oesophageal spasm	3	(
Pylorospasm	1	(
Gastrointestinal stenosis and obstru		
Intestinal obstruction	3	(
Neonatal intestinal obstruction	1	0
Gastrointestinal vascular malformati	ons	
Gastric antral vascular ectasia	10	(

Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	(
Omental infarction	1	(
Thrombosis mesenteric vessel	2	(
Visceral venous thrombosis	1	(
Gingival disorders, signs and symptoms NEC		
Gingival blister	11	(
Gingival discomfort	7	(
Gingival disorder	4	(
Gingival erythema	2	(
Gingival hypertrophy	1	(
Gingival oedema	1	(
Gingival pain	98	(
Gingival pruritus	1	(
Gingival swelling	32	(
Gingival ulceration	1	(
Gingivitis ulcerative	1	(
Noninfective gingivitis	8	(
Gingival haemorrhages		
Gingival bleeding	59	(
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Gastric varices	1	(
Haemorrhoidal haemorrhage	1	(
Haemorrhoids	31	-
Haemorrhoids thrombosed	1	(
Inguinal hernias		
Inguinal hernia	1	(
Intestinal haemorrhages		
Anal haemorrhage	20	
Intestinal haemorrhage	1	(
Rectal haemorrhage	66	(
Small intestinal haemorrhage	5	(
Intestinal ulcers and perforation NEC		
Intestinal perforation	5	2
Large intestinal ulcer	1	(
Large intestine perforation	1	(
Large intestinal stenosis and obstruction		
Large intestinal obstruction	1	
Malabsorption syndromes		
Bile acid malabsorption	2	(
Coeliac disease	10	(
Malabsorption	1	(
Steatorrhoea	4	(
Nausea and vomiting symptoms		
Discoloured vomit	12	(
Infantile vomiting	7	
Nausea	12661	
Regurgitation	1	
Retching	97	
Vomiting	4006	
Vomiting projectile	56	
Non-mechanical ileus		

Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
lleus paralytic	2	
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	15	
Haematemesis	28	
Haematochezia	50	
Melaena	8	
Upper gastrointestinal haemorrhage	11	
Oesophageal stenosis and obstruction		
Oesophageal stenosis	3	
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	
Oesophagitis	3	
Oral dryness and saliva altered		
Aptyalism	3	
Dry mouth	452	
Lip dry	37	
Saliva altered	6	
Salivary hypersecretion	47	
Oral soft tissue disorders NEC	77	
Angina bullosa haemorrhagica	1	
Chapped lips	20	
Cheilitis	20	
Enlarged uvula	14	
Leukoplakia oral	2	
Lip blister	27	
Lip disorder	4	
Oral disorder	16	
Oral lichen planus	11	
Oral mucosal hypertrophy	1	
Oral papule	1	
Uvulitis	4	
Oral soft tissue haemorrhages		
Mouth haemorrhage	15	
Oral blood blister	13	
Oral purpura	2	
Oral soft tissue infections		
Angular cheilitis	3	
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	
Burning mouth syndrome	6	
Coating in mouth	1	
Hypoaesthesia oral	440	
Lip discolouration	7	
Lip erythema	4	
Lip exfoliation	5	
Lip pain	50	
	14	
Lip pruritus	14	
Lip scab	70	
Oral discomfort	76	
Oral dysaesthesia	1	
Oral mucosal blistering	13	
Oral mucosal discolouration	1	
Oral mucosal eruption	14	

Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Oral mucosal erythema	5	
Oral mucosal exfoliation	9	
Oral mucosal roughening	3	
Oral mucosal scab	1	
Oral pain	153	
Oral pruritus	20	
Paraesthesia oral	852	
Pigmentation lip	1	
Oral soft tissue swelling and oedema		
Lip oedema	4	
Lip swelling	688	
Mouth swelling	85	
Oedema mouth	4	
Palatal oedema	3	
Palatal swelling	2	
Pancreatic disorders NEC		
Pancreatic mass	1	
Peptic ulcers and perforation		
Peptic ulcer	1	
Peptic ulcer haemorrhage	11	
Peritoneal and retroperitoneal disorders		
Ascites	1	
Peritoneal and retroperitoneal fibrosis and adhesions	1	
Abdominal adhesions	2	
	2	
Peritoneal and retroperitoneal haemorrhages	4	
Haemoperitoneum		
Retroperitoneal haemorrhage		
Rectal inflammations NEC		
Proctitis	3	
Proctitis ulcerative	1	
Salivary gland disorders NEC		
Salivary gland disorder	1	
Salivary gland pain	12	
Salivary gland enlargements		
Parotid gland enlargement	10	
Salivary gland enlargement	5	
Submaxillary gland enlargement	7	
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	
Stomatitis and ulceration		
Aphthous ulcer	47	
Lip ulceration	16	
Mouth ulceration	407	
Oral mucosa erosion	1	
Palatal ulcer	1	
Stomatitis	59	
Tongue disorders		
Glossitis	17	
Hypertrophy of tongue papillae	1	
	0	
Plicated tongue	3	
Tongue disorder	34	
Tongue geographic Tongue haemorrhage	2	

Reaction Name		Total	Fatal
Gastrointestinal disorders	Gastrointestinal disorders cont'd		
Tongue ulceration		29	0
Trichoglossia		4	0
Tongue signs and sympto	ms		
Glossodynia		193	0
Scalloped tongue		5	0
Stiff tongue		4	0
Swollen tongue		442	0
Tongue blistering		17	0
Tongue coated		16	0
Tongue discolouration		34	0
Tongue discomfort		38	0
Tongue dry		13	0
Tongue eruption		9	0
Tongue erythema		10	0
Tongue exfoliation		1	0
Tongue movement distu	Irbance	6	0
Tongue oedema		21	0
Tongue pruritus		2	0
Tongue rough		4	0
Tongue spasm		9	0
Tooth missing			
Tooth loss		6	0
Gastrointestinal disorders S	OC TOTAL	34048	18

eaction Name	Total	Fatal
eneral disorders		
Administration site reactions NEC	7	
Administration site bruise	7	
Administration site erythema	4	
Administration site extravasation	3	
Administration site haematoma	3	
Administration site inflammation	1	
Administration site irritation	1	
Administration site joint discomfort	1	
Administration site joint movement impairment	1	
Administration site nerve damage	1	
Administration site pain	17	
Administration site rash	5	
Administration site reaction	1	
Administration site swelling	4	
Administration site urticaria	2	
Administration site warmth	2	
Puncture site bruise	35	
Puncture site pain	6	
Puncture site reaction	1	
Puncture site swelling	2	
Vessel puncture site bruise	2	
Vessel puncture site erythema	1	
Vessel puncture site pain	1	
Adverse effect absent		
No adverse event	3	
Application and instillation site reactions		
Application site acne	2	
Application site bruise	8	
Application site burn	1	
Application site erythema	15	
Application site haemorrhage	1	
Application site hypoaesthesia	1	
Application site irritation	1	
Application site joint erythema	1	
Application site joint pain	1	
Application site mass	1	
Application site odour	2	
Application site pain	12	
Application site pruritus	4	
Application site rash	2	
Application site reaction	1	
Application site swelling	2	
Application site vesicles	8	
Application site warmth	1	
Instillation site warmth	8	
Asthenic conditions		
Asthenia	1720	
Chronic fatigue syndrome	70	
Decreased activity	9	
Fatigue	20312	
Malaise	4649	
Sluggishness	13	
Body temperature altered		

Reaction Name General disorders cont'd	Total	Fatal
Hyperthermia	6	C
Hypothermia	22	C
Temperature regulation disorder	12	C
Breast complications associated with device		
Breast implant palpable	1	C
Capsular contracture associated with breast implant	1	C
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	C
Complications associated with device NEC		
Capsular contracture associated with implant	1	C
Complication of device removal	3	(
Injury associated with device	4	C
Medical device pain	1	C
Medical device site swelling	1	(
Phantom shocks	2	C
Death and sudden death		
Brain death	3	3
Cardiac death	2	2
Clinical death	1	1
Death	161	161
Decapitation	1	1
Drowning	1	C
Sudden death	27	27
Febrile disorders	21	21
Hyperpyrexia	9	C
Pyrexia	13295	C
Feelings and sensations NEC	10200	Ū
Chills	8432	C
Feeling abnormal	1457	C
Feeling cold	1457	C
Feeling drunk	75	(
Feeling hot	1044	
		C
Feeling jittery	23	
Feeling of body temperature change	295	(
Feeling of relaxation	3	, c
Hangover	74	(
Hunger	42	(
Sensation of blood flow	3	(
Sensation of foreign body	48	(
Temperature intolerance	41	(
Thirst	309	(
Fibrosis NEC		
Fibrosis	1	(
Gait disturbances		
Gait disturbance	206	(
Gait inability	75	(
Loss of control of legs	18	(
General signs and symptoms NEC		
Adhesion	1	(
Chronic disease	1	(
Condition aggravated	197	(
Crepitations	2	(
Crying	145	(

Reaction Name General disorders General disorders cont'd	Total	Fatal
Deformity	2	
Discharge	11	
Disease progression	2	
Disease recurrence	27	
Effusion	21	
Energy increased	20	
Exercise tolerance decreased	20	
Foaming at mouth	24	
General physical health deterioration	15	
General symptom	3	
Glassy eyes	3	
High-pitched crying	3	
Illness	1694	
Induration	15	
Influenza like illness	2124	
Irritability postvaccinal	2124	
Local reaction	77	
	3	
Moaning Multiple organ dysfunction syndrome		
Nonspecific reaction	10	
Organ failure		
Perforation	2	
Peripheral swelling	3226	
Physical deconditioning	2	
Pre-existing condition improved	8	
Prolapse	20	
Screaming	20	
Secretion discharge		
Swelling	2634	
Swelling face	743	
Symptom recurrence Terminal state		
Tissue irritation	1	
Healing abnormal NEC	1	
Impaired healing	1	
Implant and catheter site reactions	0	
Implant site discolouration	2	
Implant site pain	3	
Implant site rash	1	
Implant site swelling	2	
Implant site urticaria	1	
Implant site warmth	3	
Inflammations		
Granuloma	1	
Inflammation	423	
Papillitis	1	
Scar inflammation	1	
Serositis	1	
Systemic inflammatory response syndrome	2	
Infusion site reactions		
Infusion site coldness	1	
Infusion site discolouration	1	
Infusion site erythema	1	

Reaction Name General disorders General disorders cont'd	Total	Fatal
Infusion site joint effusion	1	(
Infusion site joint pain	2	(
Infusion site mass	1	(
Infusion site nerve damage	1	(
Infusion site pain	1	(
Infusion site pruritus	1	(
Infusion site swelling	1	(
Infusion site urticaria	1	(
Infusion site warmth	2	(
Injection site reactions		
Injected limb mobility decreased	27	(
Injection site bruising	59	(
Injection site coldness	1	(
Injection site cyst	2	(
Injection site discolouration	5	
Injection site discomfort	10	(
Injection site eczema	1	(
Injection site erythema	342	(
Injection site extravasation	1	(
Injection site haemorrhage	6	(
Injection site hypersensitivity	2	(
Injection site hypoaesthesia	9	(
Injection site indentation	9	(
	3	(
Injection site induration	37	(
Injection site inflammation	57	
Injection site irritation		(
Injection site joint discomfort	2	(
Injection site joint erythema	2	(
Injection site joint movement impairment	1	(
Injection site joint pain	13	(
Injection site lymphadenopathy	1	(
Injection site macule	1	(
Injection site mass	474	(
Injection site movement impairment	1	(
Injection site necrosis	4	(
Injection site nerve damage	1	(
Injection site oedema	15	(
Injection site pain	2677	(
Injection site paraesthesia	12	(
Injection site pruritus	176	(
Injection site rash	152	(
Injection site reaction	29	(
Injection site scab	4	(
Injection site scar	5	(
Injection site swelling	267	(
Injection site urticaria	28	
Injection site vesicles	9	
Injection site warmth	170	
Interactions		
Alcohol interaction	А	
	25	
Drug interaction		
Inhibitory drug interaction <i>Mass conditions NEC</i>	3	

Reaction Name General disorders General disorders cont'd	Total	<u>Fatal</u>
Cyst	40	
Mass	61	
Nodule	34	
Mucosal findings abnormal	54	
Mucosa vesicle	1	
Mucosal dryness	1	
Mucosal haemorrhage	9	
Mucosal inflammation	2	
Oedema mucosal	1	
Polyp	5	
Necrosis NEC	0	
Fat necrosis	3	
Necrosis	4	
Oedema NEC		
Face oedema	28	
Generalised oedema	3	
Localised oedema	17	
Oedema	70	
Oedema peripheral	82	
Pain and discomfort NEC	02	
Axillary pain	2744	
Chest discomfort	1516	
Chest pain	3923	
Discomfort	428	
Facial discomfort	19	
Facial pain	190	
Inflammatory pain	130	
Non-cardiac chest pain	25	
Pain	7857	
Suprapubic pain	1007	
Tenderness	599	
Visceral pain	599	
•	2	
Therapeutic and nontherapeutic responses Adverse drug reaction	56	
Adverse event	50	
Adverse food reaction	3	
Adverse reaction	3	
Drug ineffective	290	
Drug intolerance	290	
Drug resistance	4	
Immediate post-injection reaction	2	
Inadequate analgesia	8	
No reaction on previous exposure to drug	36	
Product intolerance	30	
Therapeutic product effect decreased	1	
Therapeutic product effect delayed	2	
Therapeutic product effect increased		
Therapeutic product ineffective	2	
Therapeutic response decreased	2	
Therapeutic response unexpected	70	
Therapy non-responder	1	
Treatment failure	6	
Vaccination failure	38	

	Total	Fatal
General disorders General disorders cont'd		
Trophic disorders	-	
Atrophy	2	
Calcinosis	2	
Hyperplasia	1	0
Ulcers NEC		
Ulcer	30	
Ulcer haemorrhage	1	0
Vaccination site reactions	_	
Extensive swelling of vaccinated limb	12	
Shoulder injury related to vaccine administration	26	
Vaccination site anaesthesia	1	0
Vaccination site bruising	115	
Vaccination site coldness	3	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	14	
Vaccination site discomfort	45	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	573	
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	20	0
Vaccination site hypersensitivity	3	0
Vaccination site hypoaesthesia	16	0
Vaccination site induration	71	0
Vaccination site inflammation	51	
Vaccination site irritation	12	
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	9	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	17	0
Vaccination site joint pain	31	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	6	0
Vaccination site macule	1	0
Vaccination site mass	259	0
Vaccination site movement impairment	84	0
Vaccination site nerve damage	1	0
Vaccination site nodule	3	0
Vaccination site oedema	3	0
Vaccination site pain	2001	0
Vaccination site paraesthesia	7	C
Vaccination site phlebitis	1	C
Vaccination site pruritus	148	C
Vaccination site rash	119	C
Vaccination site reaction	31	
Vaccination site scab	2	
Vaccination site scar	1	
Vaccination site swelling	527	
Vaccination site thrombosis	1	
Vaccination site ulcer	1	

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	253	0
Vascular complications associated with device		
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	37	0
General disorders SOC TOTAL	92594	203

Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	12	0
Cholangitis	1	0
Cholecystitis and cholelithiasis		
Cholecystitis	3	0
Cholecystitis acute	2	0
Cholelithiasis	10	0
Cholestasis and jaundice		
Cholestasis	2	0
Jaundice	22	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
Gallbladder disorders NEC		
Gallbladder disorder	1	0
Hepatic and hepatobiliary disorders NEC		
Liver disorder	12	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	7	0
Hepatic failure and associated disorders		
Acute hepatic failure	1	0
Hepatic failure	2	1
Hepatic fibrosis and cirrhosis		
Hepatic cirrhosis	1	0
Hepatic vascular disorders		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	6	0
Hepatobiliary signs and symptoms		
Hepatic pain	26	0
Hepatomegaly	2	0
Liver tenderness	3	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	7	0
Drug-induced liver injury	2	0
Hepatic steatosis	2	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	18	0
Hepatic disorders SOC TOTAL	174	1

Reaction Name	Total	Fatal
mmune system disorders		
Acute and chronic sarcoidosis		
Sarcoidosis	15	
Allergic conditions NEC		
Allergic oedema	15	
Allergy to animal	1	
Allergy to arthropod bite	6	
Allergy to arthropod sting	2	
Allergy to metals	1	
Allergy to sting	1	
Hypersensitivity	886	
Infusion related hypersensitivity reaction	3	
Mite allergy	3	
Multiple allergies	9	
Serum sickness	2	
Serum sickness-like reaction	6	
Type I hypersensitivity	1	
Type III immune complex mediated reaction	4	
Type IV hypersensitivity reaction	6	
Allergies to foods, food additives, drugs and other chemicals	0	
Allergic reaction to excipient	5	
•	5	
Allergy to chemicals	3	
Allergy to vaccine	36	
Contrast media reaction	2	
Drug hypersensitivity	26	
Food allergy	27	
Milk allergy	2	
Oral allergy syndrome	2	
Reaction to colouring	1	
Reaction to excipient	9	
Reaction to preservatives	5	
Rubber sensitivity	1	
Smoke sensitivity	1	
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	464	
Anaphylactic shock	52	
Anaphylactoid reaction	20	
Anaphylactoid shock	4	
Atopic disorders		
Atopy	1	
Seasonal allergy	104	
Autoimmune disorders NEC		
Autoimmune disorder	40	
Immune and associated conditions NEC		
Anamnestic reaction	1	
Bacille Calmette-Guerin scar reactivation	51	
Cytokine storm	1	
Decreased immune responsiveness	2	
Graft versus host disease	1	
	0	
Haemophagocytic lymphohistiocytosis	2	
Immune reconstitution inflammatory syndrome	1	
Immune system disorder	21	
Immune-mediated adverse reaction	7	
Immunisation reaction	1	

Reaction Name	Total	Fatal
Immune system disorders Immune system disorders cont'd		
Multisystem inflammatory syndrome in children	1	0
Sensitisation	5	0
Systemic immune activation	2	0
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	3	0
Primary immunodeficiency syndromes		
Selective IgA immunodeficiency	1	0
Transplant rejections		
Corneal graft rejection	6	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	1	0
Immune system disorders SOC TOTAL	1877	2

Reaction Name	Total	Fatal
nfections		
Abdominal and gastrointestinal infections		
Abdominal abscess	2	0
Abdominal infection	1	
Anal abscess	3	0
Appendicitis	38	
Appendicitis perforated	7	0
Diverticulitis	11	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	26	
Mesenteric abscess	1	0
Peritonitis	2	1
Rectal abscess	1	0
Adenoviral infections		
Adenoviral conjunctivitis	1	0
Aspergillus infections		
Bronchopulmonary aspergillosis	1	0
Bacterial infections NEC		
Abscess bacterial	2	C
Arthritis bacterial	4	C
Bacterial colitis	1	0
Bacterial diarrhoea	1	C
Bacterial infection	13	C
Bacterial sepsis	1	0
Cellulitis	166	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	16	C
Gangrene	1	0
Injection site cellulitis	2	C
Meningitis bacterial	3	0
Paronychia	3	C (
Perichondritis	1	
Periorbital cellulitis	1	0
Sinusitis bacterial	1	0
Skin bacterial infection	2	C
Tonsillitis bacterial	3	C
Urinary tract infection bacterial	1	C
Vaccination site cellulitis	19	C
Zoonotic bacterial infection	1	1
Bartonella infections		
Cat scratch disease	1	
Bone and joint infections		
Abscess jaw	1	
Arthritis infective	1	
Osteomyelitis	2	
Borrelial infections		
Lyme disease	2	
Relapsing fever	2	
Breast infections		
Breast abscess	3	0
Mastitis	71	
Caliciviral infections		

Reaction Name Infections Infections cont'd	Total	Fatal
Gastroenteritis norovirus	3	(
	3	(
Campylobacter infections	1	
Campylobacter gastroenteritis		
Campylobacter infection	-	(
Candida infections		
Anal candidiasis	3	
Balanitis candida	1	(
Candida infection	61	
Oral candidiasis	36	
Respiratory moniliasis	1	(
Skin candida	1	(
Systemic candida	1	(
Urinary tract candidiasis	1	(
Vulvovaginal candidiasis	45	(
Cardiac infections		
Cardiac infection	1	(
Pericarditis infective	2	(
Central nervous system and spinal infections		
Brain abscess	1	(
CNS ventriculitis	1	(
Cavernous sinus thrombosis	1	0
Encephalitis	19	(
Encephalomyelitis	1	0
Meningitis	7	
Meningitis aseptic	3	
Myelitis	6	
Subdural abscess	1	
Clostridia infections		
Clostridium difficile infection	2	
Coronavirus infections		
Asymptomatic COVID-19	15	
COVID-19	1325	
COVID-19 pneumonia	48	
Coronavirus infection	7	
Post-acute COVID-19 syndrome	2	
Severe acute respiratory syndrome	2	
Suspected COVID-19	66	
Coxiella infections	00	
Q fever	11	
Cytomegaloviral infections		
Cytomegalovirus infection	2	
Cytomegalovirus syndrome	1	
Dental and oral soft tissue infections	1	
Abscess oral	6	
	10	
Gingivitis Oral infection	10	
Parotitis	10	
	10	
Pericoronitis	2	
Pulpitis dental	1	
Sialoadenitis	3	
Tongue abscess	1	
Tooth abscess	8	
Tooth infection	9	

Reaction Name	Total	Fatal
Ear infections		
Ear infection	81	0
Labyrinthitis	98	0
Mastoiditis	1	0
Otitis externa	2	0
Otitis media	2	0
Otitis media acute	1	0
Otitis media chronic	4	0
Ectoparasitic infestations		
Acarodermatitis	4	0
Bed bug infestation	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	24	0
Escherichia infections		
Escherichia bacteraemia	1	0
Eye and eyelid infections		
Conjunctivitis	67	0
Eye abscess	1	0
Eye infection	19	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	27	
Keratouveitis	21	0
		0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	15	0
Fungal skin infection	5	0
Onychomycosis	1	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	7	0
Hepatitis virus infections		
Hepatitis A	1	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	2	0
Cholecystitis infective	2	0
Hepatic infection	1	
Herpes viral infections	-	
Eczema herpeticum	2	C
Genital herpes	78	
Genital herpes simplex	6	
Herpes ophthalmic	3	

Reaction Name Infections Infections cont'd	Total	Fatal
Herpes simplex	25	0
Herpes simplex encephalitis	1	
Herpes simplex reactivation	2	
Herpes virus infection	10	
Herpes zoster	1319	
Herpes zoster disseminated	1019	
Herpes zoster meningoencephalitis	1	
Herpes zoster nieningoencephantis Herpes zoster oticus	13	
Herpes zoster reactivation	1	
Nasal herpes	4	
Ophthalmic herpes simplex	2	
Ophthalmic herpes zoster	3	
Oral herpes	287	
Varicella	25	
Varicella zoster virus infection	23	
Infections NEC	2	, i
Abscess	36	(
Abscess limb	30	
Abscess soft tissue	1	
Catheter site infection	1	
Genital abscess	2	
Infected bite	3	
Infected cyst	2	
Infection	215	
Infection susceptibility increased	213	
Injection site abscess	1	
Injection site infection	5	
Localised infection	28	
Lymph gland infection	10	
	10	
Lymph node abscess Opportunistic infection	1	
Pathogen resistance	1	
Purulent discharge		
Respiratory tract infection	10	
Vaccination site abscess	10	
Vaccination site infection	13	
Vaccine breakthrough infection	23	
Vaccine breakinough mection	23	
Wound infection	1	
Infectious transmissions		L L
Secondary transmission	8	0
Vaccine virus shedding	0	
Influenza viral infections		
Influenza	1411	
Kiebsiella infections	1411	(
Klebsiella infection	1	
		(
Lower respiratory tract and lung infections	20	
Bronchitis	20	
Infectious pleural effusion	1	
Lower respiratory tract infection	200	
Pneumonia	125	
Pneumonia aspiration	9	6
Sputum purulent	1	(

Reaction Name	Total	Fatal
Infections Infections cont'd		
Male reproductive tract infections	-	
Epididymitis	7	
Orchitis	5	0
Prostate infection	2	0
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	0
Mumps viral infections		
Mumps	6	0
Muscle and soft tissue infections		
Abscess neck	1	0
Infective tenosynovitis	1	C
Necrotising fasciitis	2	C
Psoas abscess	1	C
Soft tissue infection	2	C
Neisseria infections		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
Orthopox viral infections		
Vaccinia virus infection	1	0
Plasmodia infections		
Malaria	3	1
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	2	l o
Prion-associated disorders		
Creutzfeldt-Jakob disease	1	c d
Retroviral infections		
Acquired immunodeficiency syndrome	1	0
HIV infection	1	
Persistent generalised lymphadenopathy	1	
Rotaviral infections		
Gastroenteritis rotavirus	1	C
Rubeola viral infections		
Measles	4	C
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	3	1
Sepsis	46	
Sepsis Sepsis syndrome	40	
Septic rash		-
Septic shock	5	
Urosepsis Skin structures and soft tissue infections	о С	C
	4	
Abscess sweat gland	1	
Acne pustular	1	
Blister infected	1	
Dermatitis infected	2	
Impetigo	10	
Infected skin ulcer	1	
Injection site pustule	2	(
Nail infection	2	(
Pustule	18	
Rash pustular	10	
Skin infection	30	(
Subcutaneous abscess	11	

Reaction Name	Total	Fatal
Infections Infections cont'd		
Sweat gland infection	1	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	38	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	6	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	3	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	3	0
Treponema infections		
Syphilis	2	0
Trypanosomal infections		
African trypanosomiasis	2	0
Tuberculous infections		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
Upper respiratory tract infections		
Acute sinusitis	4	0
Chronic sinusitis	2	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	28	0
Nasopharyngitis	945	0
Peritonsillar abscess	3	0
Pharyngitis	30	0
Rhinitis	41	0
Sinusitis	149	0
Tonsillitis	109	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	10	0
Urinary tract infections		-
Cystitis	74	0
Kidney infection	43	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	182	0
Vascular infections	102	0
Haematoma infection	1	0
Infected lymphocele	2	0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Infusion site infection	1	0
Lymphangitis	7	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	27	0
Hepatitis viral	3	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	3	1
Post viral fatigue syndrome	44	0
Sweating fever	93	0
Vestibular neuronitis	28	0
Viral diarrhoea	2	0
Viral infection	49	0
Viral labyrinthitis	4	0
Viral myocarditis	2	0
Viral pericarditis	3	0
Viral pharyngitis	17	0
Viral rash	53	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	8751	103

Reaction Name	Total	Fatal
Injuries		
Abdominal and gastrointestinal injuries NEC		
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	3	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
Accidental exposures to product		,
Accidental exposure to product	20	0
Anaesthetic and allied procedural complications	20	U
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	ے 1	0
Atmospheric pressure injuries		0
Barotitis media	1	0
	1	0
Hypobarism	I	0
Bone and joint injuries NEC	-	0
Bursa injury	2	0
Joint injury	8	0
Meniscus injury	1	0
Cardiac and vascular procedural complications		-
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
Cardiovascular injuries		
Vascular injury	7	0
Cerebral injuries NEC		
Brain contusion	4	0
Brain herniation	1	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
Chemical injuries		
Chemical burn of skin	4	0
Chemical cystitis	1	0
Chest and respiratory tract injuries NEC		
Bronchial injury	1	0
Chest crushing	10	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	53	0
Cold shock response	1	0
Frostbite	1	0
Cranial nerve injuries	1	0
Vth nerve injury	1	0
	I	0
Ear injuries NEC	4	0
Deafness traumatic	1	C

Reaction Name	Total	Fatal
Ear injury		0
Exposures associated with pregnancy, delivery and lactation		0
Exposure during pregnancy	9	0
Exposure via breast milk	131	0
Foetal exposure during pregnancy	43	
Maternal exposure before pregnancy	13	0
Maternal exposure during breast feeding	1569	
Maternal exposure during pregnancy	858	
Maternal exposure timing unspecified	10	C
Paternal exposure before pregnancy	3	C
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	C
Exposure to vaccinated person	4	C
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	C
Eye injuries NEC		
Corneal abrasion	1	C
Eye contusion	13	C
Eye injury	19	C
Foreign body in eye	3	C
Injury corneal	1	C
Periorbital haematoma	1	C
Retinal injury	2	C
Superficial injury of eye	1	C
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	C
Fractures and dislocations NEC		
Bone fragmentation	1	C
Fracture	3	C
Joint dislocation	3	(
Multiple fractures	1	(
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	(
Postoperative ileus	1	(
Procedural nausea	8	(
Procedural vomiting	2	(
Heat injuries (excl thermal burns)	2	, i
Heat cramps	2	C
Heat exhaustion	3	(
Heat illness	1	
Heat oedema	11	(
Heat stroke	3	ι (
Intentional product use issues Intentional dose omission	1	
		(
Intentional product use issue		(
Limb fractures and dislocations	-	
Atypical femur fracture	3	(
Clavicle fracture	24	(
Femoral neck fracture	1	(
Femur fracture	1	(
Fibula fracture	1	(
Hip fracture	2	(
Tibia fracture	1	(

Reaction Name	Total	Fatal
	4	
Upper limb fracture	1	C
Wrist fracture		C
Medication errors, product use errors and issues NEC		C
Circumstance or information capable of leading to medication error		C
Dose calculation error	1	
Inadequate aseptic technique in use of product Medication error	10	C
	19	C
Prescription drug used without a prescription Product use complaint	2	-
Product use issue	21	C
Vaccination error	5	C
Wrong dose	4	C
Wrong drug	11	C
Wrong technique in product usage process	5	C
Mong technique in product usage process Muscle, tendon and ligament injuries	5	U
Epicondylitis	18	C
Ligament injury	2	
Ligament sprain	9	C
Mallet finger	1	C
Muscle injury	26	C
Muscle rupture	8	C
Muscle strain	29	C
Post-traumatic neck syndrome	23	C
Tendon injury	6	C
Tendon rupture	18	C
Musculoskeletal procedural complications	10	L.
Periprosthetic osteolysis	1	C
Post laminectomy syndrome	1	C
Nerve injuries NEC		
Nerve injury	85	C
Neurological and psychiatric procedural complications	00	U
Post lumbar puncture syndrome	1	C
Post procedural stroke	1	C
Procedural dizziness	11	C
Non-occupational environmental exposures		U
Exposure to extreme temperature	2	C
Non-site specific injuries NEC	_	J
Animal scratch	1	C
Arthropod bite	5	C
Arthropod sting	5	C
Bite	1	C C
Electric shock	18	(
Fall	172	C C
Foreign body	2	(
Injury	11	(
Multiple injuries	2	(
Nervous system injury	2	(
Post concussion syndrome	1	(
Traumatic haematoma	1	(
Wound	7	
Wound complication	10	(
Wound haematoma	1	(
Wound haemorrhage	2	(

Reaction Name	Total	Fatal
njuries Injuries cont'd Vound secretion	5	
Non-site specific procedural complications	J	
Incision site pain	3	
Infusion related reaction	7	
Injection related reaction	46	
Post procedural complication	5	
Post procedural erythema	1	
Post procedural inflammation		
Post procedural pruritus		
Procedural pain Seroma	2	
	4	
Occupational exposure to SARS-CoV-2		
Occupational exposure to product		
Off label uses	07	
Off label use	97	
Overdoses NEC Overdose	40	
	46	
Pathways and sources of exposure	4	
Exposure via unknown route Pelvic fractures and dislocations		
	4	
Pelvic fracture		
Peripheral nerve injuries	4	
Axillary nerve injury		
Brachial plexus injury		
Sciatic nerve injury		
Ulnar nerve injury	4	
Poisoning and toxicity	4	
Alcohol poisoning	1	
Poisoning	11	
Toxicity to various agents	3	
Product administration errors and issues	7	
Accidental overdose	1	
Contraindicated product administered	1	
Expired product administered	13	
Extra dose administered	1	
Inappropriate schedule of product administration	525	
Incomplete course of vaccination		
Incorrect dose administered	52	
Incorrect drug administration rate	1	
Incorrect product formulation administered	2	
Incorrect route of product administration	4	
Lack of vaccination site rotation	1	
Poor quality product administered	3	
Product administered at inappropriate site	16	
Product administered to patient of inappropriate age	1	
Product administration error		
Product dose omission issue	5	
Wrong product administered	20	
Product confusion errors and issues		
Product label confusion	1	
Product dispensing errors and issues		
Product dispensing error	3	

Reaction Name	<u>Total</u>	Fata
juneo ,		
Product monitoring errors and issues	1	
Drug monitoring procedure incorrectly performed		
Product preparation errors and issues	2	
Product preparation error	2	
Product preparation issue	5	
Product prescribing errors and issues		
Contraindicated product prescribed	2	
Product prescribing error	1	
Product selection errors and issues		
Product selection error	2	
Radiation injuries		
Radiation sickness syndrome	1	
Sunburn	21	
Renal and urinary tract injuries NEC		
Bladder injury	1	
Foreign body in urogenital tract	1	
Reproductive system and breast injuries		
Penis injury	1	
Site specific injuries NEC		
Back injury	2	
Face crushing	2	
Face injury	1	
Head injury	33	
Limb crushing injury	4	
Limb injury	102	
Nasal injury	1	
Neck crushing	1	
Neck injury	1	
Site specific procedural complications NEC		
Axillary web syndrome	1	
Skin injuries NEC		
Contusion	1113	
Nail avulsion	1113	
Scar	21	
Scratch	21	
Skin abrasion	6	
	0	
Skin injury Skin laceration	4	
Skin laceration Skin wound	3	
	3	
Splinter		
Subcutaneous haematoma	2	
Skin procedural complications		
Dermal filler overcorrection	1	
Recall phenomenon	1	
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	
Fractured skull depressed	1	
Spinal cord injuries NEC		
Spinal cord injury cervical	1	
Spinal fractures and dislocations		
Spinal fracture	4	
Stoma complications		
Gastrointestinal stoma complication	2	

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	4	0
Burns second degree	6	0
Burns third degree	4	0
Thermal burn	20	0
Thermal burns of eye	12	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Vaccination complication	48	0
Injuries SOC TOTAL	5831	1

Reaction Name	Total	Fatal
nvestigations		
Adrenal cortex tests	_	
Cortisol decreased	4	
Adrenal medulla tests	_	
Epinephrine abnormal	1	
Epinephrine increased	1	
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	
Audiogram abnormal	1	
Autoimmunity analyses		
Antinuclear antibody	1	
Antinuclear antibody increased	1	
Antinuclear antibody positive	2	
Rheumatoid factor	3	
Bacteria identification and serology (excl mycobacteria)		
Bacterial test positive	1	
Klebsiella test positive	1	
Blood counts NEC		
Full blood count	5	
Full blood count abnormal	2	
Blood gas and acid base analyses		
Acid base balance abnormal	1	
Blood lactic acid	4	
Blood lactic acid decreased	1	
Blood lactic acid increased	5	
Blood pH	8	
Blood pH increased	9	
Oxygen consumption	1	
Oxygen consumption decreased	2	
Oxygen saturation	9	
Oxygen saturation decreased	66	
PO2 decreased	1	
Bone marrow and immune tissue histopathology procedures		
	1	
Aspiration bone marrow	1	
Biopsy lymph gland		
Bone marrow and immune tissue imaging procedures	1	
Lymph nodes scan abnormal	1	
Scan lymph nodes	4	
Carbohydrate tolerance analyses (incl diabetes)	0	
Blood glucose	8	
Blood glucose abnormal	12	
Blood glucose decreased	31	
Blood glucose fluctuation	15	
Blood glucose increased	95	
Blood glucose normal	1	
Glycosylated haemoglobin increased	1	
Cardiac auscultatory investigations		
Cardiac murmur	35	
Heart sounds	6	
Heart sounds abnormal	4	
Cardiac function diagnostic procedures		
Cardiac monitoring	1	
Cardiac output	1	
Central venous pressure	1	

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Echocardiogram	1	C
Ejection fraction decreased	1	C
Myocardial strain imaging	1	C
Stroke volume decreased	1	C
Cardiac imaging procedures		_
Magnetic resonance imaging heart	1	C
Scan myocardial perfusion abnormal	1	C
Cell marker analyses		_
HLA-B*27 positive	1	(
Prostatic specific antigen increased	2	(
Central nervous system imaging procedures		
Computerised tomogram head	6	(
Magnetic resonance imaging head	12	C
Magnetic resonance imaging head abnormal	1	C
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	(
Chemistry analyses NEC		
Histamine abnormal	1	(
Histamine level	1	(
Histamine level increased	1	(
Inflammatory marker decreased	1	C
Inflammatory marker increased	3	(
Renin	1	(
Cholesterol analyses		
Blood cholesterol increased	7	C
Remnant-like lipoprotein particles	3	C
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	C
Activated partial thromboplastin time shortened	1	C
Bleeding time	2	(
Bleeding time abnormal	1	(
Bleeding time prolonged	7	(
Blood thromboplastin	1	C
Clot retraction	2	1
Coagulation factor VIII level decreased	1	(
Coagulation time prolonged	9	(
Coagulation time shortened	4	(
Fibrin D dimer increased	13	(
International normalised ratio abnormal	7	(
International normalised ratio decreased	21	(
International normalised ratio fluctuation	2	(
International normalised ratio increased	50	(
Platelet factor 4	1	(
Prothrombin time shortened	1	(
Digestive enzymes		,
Amylase increased	1	(
ECG investigations		,
Electrocardiogram	6	(
	1	
Electrocardiogram QRS complex prolonged		
Electrocardiogram QT prolonged	8	
Electrocardiogram ST segment depression	_	
Electrocardiogram ST segment elevation	11	(
Electrocardiogram ST-T segment abnormal	2	

Reaction Name	Total	Fatal
nvestigations Investigations cont'd	-	
Electrocardiogram T wave inversion	5	
Electrocardiogram abnormal	18	
Electrocardiogram change	1	
Electrocardiogram normal	2	
Electrocardiogram repolarisation abnormality	1	
QRS axis abnormal	1	
Endocrine analyses and imaging NEC	50	
Hormone level abnormal	50	
Faecal analyses NEC		
Faecal calprotectin	2	
Faecal calprotectin increased	4	
Fertility analyses		
Infertility tests	1	
Semen analysis abnormal	1	
Sperm concentration	2	
Sperm concentration decreased	1	
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	4	
Foetal heart rate increased	1	
Foetal monitoring	1	
Foetal non-stress test	1	
Gastrointestinal and abdominal imaging procedures		
Colonoscopy	1	
Computerised tomogram abdomen	1	
Laparoscopy	1	
Sigmoidoscopy abnormal	1	
X-ray gastrointestinal tract abnormal	1	
X-ray with contrast upper gastrointestinal tract	1	
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	1	
Blood insulin decreased	1	
Haematological analyses NEC		
Blood viscosity abnormal	1	
Plasma viscosity	1	
Plasma viscosity abnormal	1	
Red blood cell sedimentation rate increased	6	
Heart rate and pulse investigations		
Carotid pulse	1	
Heart rate	415	
Heart rate abnormal	56	
Heart rate decreased	71	
Heart rate increased	816	
Heart rate irregular	188	
Heart rate normal	1	
Maximum heart rate	2	
Pulse abnormal	18	
Pulse pressure increased	1	
Radial pulse abnormal	1	
Sinus rhythm	7	
Imaging procedures NEC		
Computerised tomogram	3	

Acction Name Investigations cont'd	Total	Fata
Magnetic resonance imaging	4	
Magnetic resonance imaging abnormal	1	
Scan	2	
X-ray	1	
Immune response protein analyses NEC		
Cytokine test	1	
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	
Blood immunoglobulin M	1	
Blood immunoglobulin M increased	1	
Immunoglobulins	1	
Immunology analyses NEC		
Antibody test	4	
Immunology test	10	
Immunology skin tests NEC		
Skin test positive	1	
Investigations NEC		
Blood test	23	
Blood test abnormal	45	
False positive investigation result	1	
Laboratory test	1	
Polymerase chain reaction	1	
Polymerase chain reaction positive	33	
Quality of life decreased	2	
Systemic lupus erythematosus disease activity index increased	1	
Liver function analyses		
Alanine aminotransferase increased	24	
Aspartate aminotransferase	1	
Aspartate aminotransferase abnormal	1	
Aspartate aminotransferase increased	2	
Blood bilirubin increased	4	
Gamma-glutamyltransferase increased	4	
Hepatic enzyme increased	6	
Liver function test	1	
Liver function test abnormal	27	
Liver function test increased	24	
Transaminases increased	5	
Metabolism tests NEC		
Blood ketone body	3	
Blood ketone body increased	1	
Blood ketone body present	1	
Blood uric acid increased	2	
Brain natriuretic peptide increased	1	
Ubiquinone	1	
Urine ketone body present	1	
Microbiology and serology tests NEC		
Culture negative	1	
Culture throat	1	
Culture urine	1	
Mineral and electrolyte analyses		
Blood copper increased	1	
Blood iron	2	
Blood iron decreased	9	

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	3	0
Blood sodium decreased	10	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	7	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		Ŭ
Coma scale abnormal	4	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	7	0
Temperature perception test abnormal	1	0
	1	0
Temperature perception test increased		U
Ophthalmic function diagnostic procedures Corneal reflex decreased	1	0
		0
Intraocular pressure increased		0
Intraocular pressure test	1	0
Physical examination procedures and organ system status	005	
Body temperature	235	0
Body temperature abnormal	40	
Body temperature decreased	38	0
Body temperature fluctuation	45	0
Body temperature increased	389	0
Body temperature normal	1	0
Breath sounds	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	22	0
Head lag	7	0
Lymph node palpable	38	0
Menstruation normal	2	C
Muscle strength abnormal	1	C
Ophthalmological examination	2	C
Orthopaedic examination	1	0
Palpatory finding abnormal	2	C
Product residue present	2	(
Psoriasis area severity index decreased	2	
Respiratory rate	10	
Respiratory rate decreased	20	
Respiratory rate increased	36	

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Skin temperature	39	(
Temperature difference of extremities	10	(
Weight	1	
Weight decreased	97	
Weight increased	35	
Pituitary analyses anterior		
Blood corticotrophin	1	
Blood follicle stimulating hormone increased	1	
Blood growth hormone	3	
Blood prolactin	2	
Blood prolactin increased		
Blood thyroid stimulating hormone decreased	2	
Blood thyroid stimulating hormone increased	5	
Platelet analyses		
Mean platelet volume decreased	1	
Mean platelet volume increased	1	
Platelet count	3	
Platelet count abnormal	1	
Platelet count decreased	70	
Platelet count increased	5	
Protein analyses NEC		
Alpha 1 globulin decreased	1	
Alpha 2 globulin decreased	1	
C-reactive protein increased	18	
Red blood cell analyses		
Haematocrit	1	
Haematocrit decreased	1	
Haematocrit increased	1	
Haemoglobin	2	
Haemoglobin decreased	11	
Haemoglobin increased	1	
Red blood cell count decreased	2	
Red blood cell rouleaux formation present	1	
Renal function analyses		
Blood creatinine	1	
Blood creatinine increased	3	
Glomerular filtration rate decreased	3	
Reproductive hormone analyses		
Blood oestrogen decreased	2	
Blood testosterone decreased	1	
Blood testosterone increased	1	
False negative pregnancy test	1	
Female sex hormone level	3	
Human chorionic gonadotropin increased	1	
Pregnancy test	18	
Pregnancy test false positive	1	
Pregnancy test positive	1	
Reproductive organ and breast histopathology procedures		
Biopsy breast	1	
Biopsy endometrium	1	
Smear cervix	2	
Reproductive organ and breast imaging procedures		
Breast scan	1	

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Hysteroscopy	2	(
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	(
Fractional exhaled nitric oxide normal	1	(
Maximal voluntary ventilation	1	(
Peak expiratory flow rate	1	(
Peak expiratory flow rate decreased	4	(
Pulmonary function test	3	(
Total lung capacity decreased	3	(
Vital capacity	1	(
Respiratory tract and thoracic histopathology procedures Sputum abnormal	3	(
	3	(
Respiratory tract and thoracic imaging procedures	18	
Chest X-ray	10	
Chest X-ray abnormal		(
Chest X-ray normal	2	(
Chest scan	2	(
Computerised tomogram thorax	1	(
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	7	(
Muscle enzyme	1	(
Myocardial necrosis marker	1	(
Myocardial necrosis marker increased	2	(
Troponin I increased	1	(
Troponin T increased	1	(
Troponin increased	14	(
Therapeutic drug monitoring analyses		
Analgesic drug level	4	(
Anticoagulation drug level above therapeutic	1	(
Anticoagulation drug level below therapeutic	5	(
Anticoagulation drug level increased	1	(
Drug level decreased	1	(
Thyroid analyses		
Anti-thyroid antibody	1	(
Thyroid function test abnormal	4	(
Thyroxine free increased	2	(
Tri-iodothyronine	1	(
Tri-iodothyronine decreased	6	(
Tissue enzyme analyses NEC	Ĭ	
Blood alkaline phosphatase increased	5	(
Enzyme level increased	1	
Toxicology laboratory analyses		
Blood caffeine decreased	1	
Blood lead	1	
Drug screen positive	2	
Opiates	1	
Urinalysis NEC		
Blood urine	15	
Blood urine present	48	
Cells in urine	1	
Glucose urine present	1	
Protein urine absent	1	
Urine analysis abnormal	6	

InvestigationsInvestigations cont'dUrine uric acid increased1pH urine5pH urine increased2Urinary tract function analyses NEC13Urine output13Urine output decreased13Urine output increased6Urinary tract histopathology procedures1Urinary tract imaging procedures1Urinary tract imaging procedures2Ultrasound kidney normal1Vascular imaging procedures NEC2Venogram2Vascular tests NEC (incl blood pressure)7Blood pressure decreased73Blood pressure diastolic2Blood pressure diastolic cecreased1Blood pressure diastolic increased2Blood pressure diastolic increased2Blood pressure diastolic increased2Blood pressure increased2	
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Blood pressure diastolic2Blood pressure diastolic decreased1Blood pressure diastolic increased2	
Blood pressure diastolic decreased1Blood pressure diastolic increased2	0
Blood pressure diastolic increased 2	0
	0
Blood pressure increased 213	0
	0
Blood pressure measurement 34	0
Blood pressure normal 2	0
Blood pressure systolic 1	0
Blood pressure systolic decreased 3	0
Blood pressure systolic increased 1	0
Virus identification and serology	
Coronavirus test 11	0
Coronavirus test positive 4	0
Epstein-Barr virus test positive 1	0
HIV test 1	0
SARS-CoV-1 test 1	0
SARS-CoV-1 test positive 1	0
SARS-CoV-2 antibody test 12	0
SARS-CoV-2 antibody test negative 15	0
SARS-CoV-2 antibody test positive 4	C
SARS-CoV-2 test 35	0
SARS-CoV-2 test false negative 3	C
SARS-CoV-2 test false positive 4	C
SARS-CoV-2 test negative 8	C
SARS-CoV-2 test positive 97	C
Viral test 4	C
Viral test positive 1	C
Vitamin analyses	
Blood folate decreased 6	C
Vitamin B12 1	C
Vitamin B12 abnormal	ĺ
Vitamin B12 decreased 2	(
Vitamin D 2	(
Vitamin D decreased 3	(
Water and electrolyte analyses NEC	, in the second s
Urine osmolarity 1	ſ
Volume blood 1	(

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
White blood cell analyses		
Eosinophil count	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	2	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	1	0
Neutrophil count	2	0
Neutrophil count decreased	9	0
Neutrophil count increased	3	0
White blood cell count	3	0
White blood cell count decreased	11	0
White blood cell count increased	11	0
Investigations SOC TOTAL	4686	3

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	16	(
Decreased appetite	1088	(
Diet refusal	1	(
Eating disorder symptom	2	(
Food craving	12	(
Food refusal	14	(
Hyperphagia	15	(
Hypophagia	17	(
Increased appetite	32	
Salt craving	2	
Calcium metabolism disorders		
Hypocalcaemia	3	(
Tetany	3	
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	46	
Diabetes mellitus inadequate control	14	
Increased insulin requirement	2	
Insulin resistant diabetes	1	
Latent autoimmune diabetes in adults	2	
Type 1 diabetes mellitus	15	
Type 2 diabetes mellitus	4	
Diabetic complications NEC		
Diabetic complication	2	
Diabetic ketoacidosis	11	
Diabetic ketosis	1	
Disorders of purine metabolism		
Gout	89	
Electrolyte imbalance NEC		
Electrolyte imbalance	1	
Fluid imbalance	2	
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	4	
Fluid intake decreased		
Fluid intake reduced	1	
Fluid intake increased		
Polydipsia	6	
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Alcohol intolerance	3	
Breast milk substitute intolerance	1	
Dairy intolerance	3	
Food intolerance	16	
Gluten sensitivity	7	
Histamine intolerance	4	
General nutritional disorders NEC		
Abnormal loss of weight	19	
Abnormal weight gain	19	
Cachexia	1	
Feeding disorder	70	
Food aversion	8	
Malnutrition	1	
Neonatal insufficient breast milk syndrome	3	
Obesity	1	

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Overweight	1	C
Poor feeding infant	15	C
Weight loss poor	3	C
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	C
Hyperglycaemia	65	0
Insulin resistance	4	C
Hypoglycaemic conditions NEC		
Glycopenia	1	C
Hypoglycaemia	75	0
Hypoglycaemia unawareness	1	C
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	11	0
Iron excess		
Haemochromatosis	1	0
Iron overload	1	
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	5	1
Lactic acidosis	2	C
Metabolic acidosis	2	
Metabolic disorders NEC	_	
Hypercatabolism	1	C
Metabolic disorder	1	
Mixed acid-base disorders		
Acidosis	4	C
Potassium imbalance		
Hyperkalaemia	5	C
Hypokalaemia	3	
Hypokalaemic syndrome	1	
Sodium imbalance		
Hyponatraemia	8	C
Hyponatraemic syndrome	3	
Salt intoxication	1	
Sugar intolerance (excl glucose intolerance)	1	
Lactose intolerance	2	C
Total fluid volume decreased	2	
Dehydration	192	C
Total fluid volume increased	192	
Fluid retention	50	
	50	
Hypervolaemia	5	L L
Vitamin deficiencies NEC		
Hypovitaminosis	6	(
Water soluble vitamin deficiencies		
Folate deficiency	4	(
Vitamin B12 deficiency	5	(
Metabolic disorders SOC TOTAL	2043	

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	272	0
Arthropathy	25	0
Autoimmune arthritis	7	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	15	0
Rheumatic fever	2	0
Sacroiliitis	5	0
Seronegative arthritis	2	0
Bone disorders NEC		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	4	0
Osteitis	6	C
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
Bone related signs and symptoms	1	0
	334	0
Bone pain	334	0
Bone swelling		0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	342	0
Pubic pain	2	0
Spinal pain	68	0
Bursal disorders		
Bursitis	65	0
Cartilage disorders		
Chondritis	1	0
Costochondritis	81	0
Osteochondritis	1	0
Polychondritis	3	0
Connective tissue disorders NEC		
Connective tissue disorder	1	0
Polymyalgia rheumatica	55	C
Reynold's syndrome	1	C
Sjogren's syndrome	5	C
Systemic scleroderma	1	C
Crystal arthropathic disorders		
Chondrocalcinosis pyrophosphate	2	C
Crystal arthropathy	1	(
Epiphyseal disorders		
Epiphyses premature fusion	1	C
Extremity deformities		
Bone deformity	1	(
Finger deformity	2	(
	2	
Foot deformity		(
Hand deformity	2	(
Knee deformity	1	(
Limb deformity	4	(

Reaction Name		Total	Fatal
Muscle & tissue disorders N	luscle & tissue disorders cont'd		
Musculoskeletal deformity		1	0
Fractures NEC			
Osteoporotic fracture		1	0
Intervertebral disc disorders			
Intervertebral disc protrusion	on	3	0
Joint related disorders NEC			
Chondromalacia		1	0
Hypermobility syndrome		1	0
Joint deposit		1	0
Joint destruction		1	0
Joint instability		1	0
Joint laxity		3	0
Joint lock		24	0
Patellofemoral pain syndro	me	1	0
Periarthritis		158	0
Rotator cuff syndrome		29	0
Temporomandibular joint s		8	0
Joint related signs and symp	otoms		
Arthralgia		8136	0
Jaw clicking		6	0
Joint effusion		16	0
Joint noise		34	0
Joint range of motion decre	eased	30	0
Joint stiffness		218	0
Joint swelling		492	0
Joint vibration		3	0
Joint warmth		14	0
Loose body in joint		1	0
Ligament disorders			
Ligament pain		2	0
Symphysiolysis		1	0
Lupus erythematosus (incl s	ubtypes)		
Lupus-like syndrome		1	0
Systemic lupus erythemato	osus	21	0
Metabolic bone disorders			
Osteopenia		3	0
Osteoporosis		3	0
Muscle infections and inflam	mations		
Antisynthetase syndrome		3	0
Immune-mediated myositis	3	1	0
Myositis		36	0
Polymyositis		8	0
Muscle pains			
Fibromyalgia		102	0
Myalgia		9807	1
Myalgia intercostal		1	0
Myofascial pain syndrome		11	0
Muscle related signs and syr	mptoms NEC		
Haematoma muscle		1	0
Muscle atrophy		20	0
Muscle discomfort		7	0
Muscle disorder		7	0
Muscle fatique		319	0

Reaction Name	& tissue disorders cont'd	Fatal
	& tissue disorders contid	
Muscle haemorrhage		1 (
Muscle mass		5 (
Muscle oedema		1 (
Muscle spasms	192	
Muscle swelling	3	
Muscle tightness		9 (
Muscle twitching	44	5 (
Muscle tone abnormalities		_
Muscle rigidity		5 (
Nuchal rigidity		0 0
Torticollis		6 (
Trismus	3	0 0
Muscle weakness conditions		-
Muscular weakness	85	2 0
Musculoskeletal and connective ti		-
Back disorder		2 0
Chest wall mass		1 C
Growth disorder		2 0
Limb mass	2	
Mandibular mass		2 0
Mastication disorder		4 C
Mobility decreased	10	
Muscle contracture		1 C
Musculoskeletal disorder		1 C
Musculoskeletal stiffness	114	
Posture abnormal		1 C
Sacroiliac joint dysfunction		1 C
Weight bearing difficulty Musculoskeletal and connective ti	ssue deformities of skull, face and	3 C
buccal cavity		
Head deformity		2 0
Musculoskeletal and connective ti	ssue infections and inflammations NEC	
Dactylitis		2 0
Dupuytren's contracture		1 C
Fasciitis		1 C
Plantar fasciitis		9 0
Musculoskeletal and connective ti	ssue pain and discomfort	
Back pain	218	8 C
Flank pain	6	4 C
Limb discomfort	139	2 0
Musculoskeletal chest pain	21	4 0
Musculoskeletal discomfort	9	0 0
Musculoskeletal pain	11	0 0
Neck pain	173	5 (
Pain in extremity	1161	6 1
Rheumatic disorder	1	5 (
Sacral pain		3 (
Myopathies		
Myopathy		6
Rhabdomyolysis	1	
Osteoarthropathies		
Nodal osteoarthritis		1
Osteoarthritis	4	

Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue	disorders cont'd	
Spinal osteoarthritis	1	C
Psoriatic arthropathies		
Psoriatic arthropathy	16	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	110	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	232	0
Fluctuance	1	0
Groin pain	100	0
Neck mass	33	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	6	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	7	0
Arthritis reactive	41	0
Spondylitis	3	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	18	0
Synovitis	10	
Tendon disorders		
Enthesopathy	2	0
Posterior tibial tendon dysfunction	1	
Tendon disorder	5	0
Tendon pain	20	
Tendonitis	38	
Tenosynovitis	3	0
Tenosynovitis stenosans	2	
Trigger finger	28	
Trunk deformities		
Drooping shoulder syndrome	1	
Shoulder deformity	2	
Muscle & tissue disorders SOC TOTAL	43772	-

Reaction Name	Total	Fatal
Neoplasms		
B-cell lymphomas NEC	0	
B-cell lymphoma	2	
Follicular lymphoma	3	
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	
Bone neoplasms unspecified malignancy		
Bone neoplasm	1	
Breast and nipple neoplasms benign		
Benign breast neoplasm	1	
Fibroadenoma of breast	1	
Breast and nipple neoplasms malignant		
Breast cancer	38	
Breast cancer female	1	
Breast cancer male	1	
Breast cancer stage I	1	
Breast cancer stage III	3	
Invasive ductal breast carcinoma	1	
Triple negative breast cancer	2	
Cardiovascular neoplasms benign		
Haemangioma	1	
Pericardial lipoma	1	
Cervix neoplasms malignant		
Cervix carcinoma	1	
Colorectal neoplasms malignant		
Colon cancer	1	
Colorectal cancer	1	
Rectal cancer	2	
Endocrine neoplasms malignant and unspecified NEC		
Neuroendocrine tumour	1	
Thyroid neoplasm	1	
Endometrial neoplasms malignant		
Endometrial cancer	1	
Follicular lymphomas		
Primary gastrointestinal follicular lymphoma	1	
Gastric neoplasms malignant		
Gastric cancer	1	
Gastrointestinal neoplasms malignant NEC		
Gastrointestinal carcinoma	3	
Hepatobiliary neoplasms malignancy unspecified		
Hepatic neoplasm	1	
Hodgkin's disease NEC		
Hodgkin's disease	5	
Islet cell neoplasms and APUDoma NEC		
Pancreatic neuroendocrine tumour	1	
Leukaemias NEC		
Leukaemia	4	
Leukaemias acute NEC		
Acute leukaemia	2	
Leukaemias chronic NEC		
Chronic leukaemia	1	
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	3	
Leukaemias chronic myeloid	5	

Reaction Name Neoplasms Neoplasms cont'd	Total	Fatal
	1	
Chronic myeloid leukaemia <i>Lip and oral cavity neoplasms malignant</i>		
	1	
Lip and/or oral cavity cancer recurrent	1	
Lymphomas unspecified NEC	30	
Lymphoma	30	
Metastases to specified sites Metastases to bone	1	
Metastases to bole Metastases to liver	1	
	5	
Metastases to lymph nodes Metastases to unknown and unspecified sites	5	
Metastasis	1	
Mycoses fungoides		
Cutaneous T-cell lymphoma	1	
Myelodysplastic syndromes	1	
Myelodysplastic syndrome	3	
	3	
Myeloproliferative disorders (excl leukaemias)	1	
Essential thrombocythaemia	1	
Neoplasms malignant site unspecified NEC Adenocarcinoma metastatic	1	
Metastatic neoplasm	2	
Neoplasm malignant	1	
Second primary malignancy	5	
Squamous cell carcinoma	5	
Neoplasms unspecified malignancy and site unspecified NEC	1	
Neoplasm	1	
Neoplasm recurrence		
Nervous system neoplasms benign NEC	1	
Cranial nerve neoplasm benign	1	
Neurilemmoma benign	1	
Nervous system neoplasms unspecified malignancy NEC	2	
Brain neoplasm	2	
Spinal cord neoplasm <i>Neuromas</i>		
Acoustic neuroma	2	
	2	
Non-Hodgkin's lymphomas NEC	2	
Non-Hodgkin's lymphoma	2	
Ocular neoplasms benign	1	
Eye naevus <i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	4	
Oncologic complications and emergencies	4	
Cancer pain	1	
Tumour haemorrhage	1	
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and	1	
nspecified		
Tonsil cancer	3	
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	1	
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic neoplasms maignant (exclusier cell and carcinold) Pancreatic carcinoma	4	
Plasma cell myelomas	4	
	4	
POEMS syndrome Plasma cell myeloma		

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Plasma cell neoplasms NEC		
TEMPI syndrome	1	(
Prostatic neoplasms malignant		
Prostate cancer	4	(
Renal neoplasms malignant		
Clear cell renal cell carcinoma	1	(
Renal cancer	2	(
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	1	(
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	1	(
Lung neoplasm malignant	11	1
Salivary gland neoplasms unspecified malignancy		
Salivary gland neoplasm	1	(
Skin melanomas (excl ocular)		
Malignant melanoma	1	(
Skin neoplasms benign		
Acrochordon	4	(
Anogenital warts	7	(
Haemangioma of skin	4	(
Melanocytic naevus	6	(
Pyogenic granuloma	1	(
Skin papilloma	18	(
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	3	(
Bowen's disease	1	(
Neoplasm skin	2	(
Squamous cell carcinoma of skin	1	(
Soft tissue neoplasms benign NEC		
Lipoma	7	(
Lymphangioma	1	(
Soft tissue sarcomas histology unspecified		
Sarcoma	1	(
Thyroid neoplasms malignant		
Papillary thyroid cancer	2	(
Thyroid cancer	1	(
Uterine neoplasms benign		
Uterine leiomyoma	10	(
Neoplasms SOC TOTAL	269	e

Reaction Name	Total	Fatal
Nervous system disorders		
Abnormal reflexes		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	7	0
Reflexes abnormal	2	0
Abnormal sleep-related events		
Sleep paralysis	25	0
Absence seizures		
Petit mal epilepsy	26	0
Acute polyneuropathies		
Acute motor axonal neuropathy	1	0
Guillain-Barre syndrome	66	1
Miller Fisher syndrome	1	0
Subacute inflammatory demyelinating polyneuropathy	1	0
Autonomic nervous system disorders		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	9	0
Autonomic neuropathy	2	0
Horner's syndrome	1	0
Orthostatic intolerance	1	0
Central nervous system aneurysms and dissections		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
Central nervous system haemorrhages and cerebrovascular accidents		
Brain stem haemorrhage	1	1
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	3	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	45	8
Cerebral infarction	27	2
Cerebral thrombosis	13	0
Cerebrovascular accident	374	16
Embolic stroke	6	0
Haemorrhage intracranial	10	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	10	3
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	C
Ischaemic stroke	46	2
Lacunar infarction	2	C
Lacunar stroke	3	C
Lateral medullary syndrome	1	C

eaction Name	Nervous system disorders cont'd	Total	Fatal
ervous system disorders	Nervous system disorders cont d		
Pseudostroke		1	
Subarachnoid haemorrh	age	14	•
Thalamic infarction		1	
Thrombotic stroke		3	5
	flammatory disorders NEC		
Arachnoiditis		1	
Gliosis		1	
Central nervous system v	ascular disorders NEC		
Brain hypoxia		2	<u></u>
Carotid arteriosclerosis		1	
Central nervous system		1	
Cerebral amyloid angior	pathy	1	
Cerebral congestion		4	•
Cerebral small vessel is		1	
Cerebrovascular disorde		2	-
Post cardiac arrest sync		1	
Reversible cerebral vas		1	
Cerebrovascular venous a			
Cerebral venous sinus t		48	
Cerebral venous thromb		6	
Superior sagittal sinus the		6	5
Transverse sinus throm		1	
Cervical spinal cord and r	erve root disorders		
Cervical radiculopathy		1	
Cervicobrachial syndron	ne	3	5
Choreiform movements			
Chorea		2	2
Chronic polyneuropathies			
	emyelinating polyradiculoneuropathy	1	
Demyelinating polyneur	opathy	1	
Coma states			
Coma		13	5
Diabetic coma		1	
Hypoglycaemic coma		1	
Coordination and balance	disturbances		
Ataxia		14	
Balance disorder		374	•
Cerebellar ataxia		1	
Coordination abnormal		54	-
Dysdiadochokinesis		1	
Dysstasia		55	
Nystagmus		11	
Cortical dysfunction NEC			
Alexia		2	2
Aphasia		78	5
Apraxia		1	
Dysgraphia		1	
Dyslexia		1	
Dyspraxia		1	
Neurologic neglect synd		1	
Sensory processing disc	order	2	2
Visuospatial deficit		1	
Cranial nerve disorders N	EC		

Reaction Name Nervous system disorders cont'd	Total	Fatal
Cranial nerve disorder	2	
Cranial nerve paralysis	1	
Dementia (excl Alzheimer's type)	10	
Dementia	18	
Dementia with Lewy bodies	1	
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	6	
Clinically isolated syndrome	1	
Demyelination	8	
Neuromyelitis optica spectrum disorder	2	
Disturbances in consciousness NEC		
Altered state of consciousness	11	0
Consciousness fluctuating	2	(
Depressed level of consciousness	45	
Infant sedation	1	0
Lethargy	2092	
Loss of consciousness	604	(
Postictal state	5	
Sedation	8	(
Somnolence	947	0
Stupor	4	0
Syncope	2047	(
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	
Irregular sleep phase	2	
Irregular sleep wake rhythm disorder	1	
Dyskinesias and movement disorders NEC		
Akathisia	5	0
Bradykinesia	18	
Clumsiness	20	
Dyskinesia	60	
Extrapyramidal disorder	2	
Fine motor skill dysfunction	11	
Foetal movement disorder	4	
Hyperkinesia	3	
Hypokinesia	69	
Motor dysfunction	4	-
Movement disorder	50	
Psychomotor hyperactivity	23	
Synkinesis		
Tardive dyskinesia	2	
Dystonias	2	
Dystonia	15	0
Writer's cramp	1	
Encephalitis NEC	1	
	1	
Encephalitis autoimmune Limbic encephalitis	1	
	5	
Noninfective encephalitis	5	
Encephalopathies NEC		
Autoimmune encephalopathy	1	
Encephalopathy	5	
Hashimoto's encephalopathy	1 1	

ervous system disorders Nervous system dis	Total	Fatal
Posterior reversible encephalopathy syndro	me i	
Eye movement disorders Illrd nerve disorder	1	
	7	
Illrd nerve paralysis	1	
IVth nerve paralysis	1	
Microvascular cranial nerve palsy Vlth nerve disorder	1	
Vith nerve paralysis	10	
Facial cranial nerve disorders	10	
Bell's palsy	472	
Facial nerve disorder	472	
Facial paralysis	363	
Facial paresis	89	
Facial spasm	47	
Generalised tonic-clonic seizures	41	
Generalised tonic-clonic seizures	54	
Headaches NEC		
Cervicogenic headache	3	
Cluster headache	213	
Cold-stimulus headache	24	
Drug withdrawal headache	24	
Exertional headache	8	
External compression headache	0	
Headache	24362	
Medication overuse headache	24302	
New daily persistent headache		
Occipital neuralgia	4	
Ophthalmoplegic migraine	1	
Primary cough headache		
Primary cough neadache Primary headache associated with sexual a	ctivity 7	
Sinus headache	329	
Tension headache	529	
	11	
Thunderclap headache Vascular headache	15	
Hydrocephalic conditions	13	
	2	
Hydrocephalus Hypoglossal nerve disorders	2	
	1	
Tongue paralysis Increased intracranial pressure disorders	I	
	1	
Brain compression Brain oedema	8	
Idiopathic intracranial hypertension	0	
Intracranial pressure increased	1	
Intellectual disabilities	2	
	2	
Intellectual disability	3	
Lumbar spinal cord and nerve root disorders		
Sciatica	89	
Memory loss (excl dementia)	475	
Amnesia	175	
Memory impairment	183	
Transient global amnesia	9	
Mental impairment (excl dementia and memo		
Cognitive disorder	84	

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Reaction Name		Total	Fatal
	ervous system disorders cont'd		
Neurotoxicity		4	C
Psychomotor skills impaire		1	C
Neurologic visual problems N	NEC		
Hemianopia		1	0
Hemianopia homonymous		2	0
Quadrantanopia		1	0
Tunnel vision		18	0
Neurological signs and symp	otoms NEC		
Agitation neonatal		1	0
Clonus		4	0
Decerebrate posture		1	0
Decorticate posture		1	0
Dizziness		9228	0
Dizziness exertional		40	0
Dizziness postural		695	0
Drooling		22	0
Fontanelle bulging		22	0
Head discomfort		2 318	
		310	0
Hyporesponsive to stimuli		2	0
Inability to crawl		2	0
Infant irritability		10	0
Meningism		1	0
Myoclonus		29	0
Neurological symptom		45	0
Patient elopement		1	0
Persistent postural-percept	tual dizziness	15	0
Presyncope		596	0
Sensory overload		4	0
Slow response to stimuli		4	0
Tongue biting		7	0
Unresponsive to stimuli		47	0
Neuromuscular disorders NE	EC		
Muscle contractions involu		23	0
Muscle spasticity	,	10	0
Neuromuscular pain		.3	0
Neuromuscular junction dysf	function	Ű	Ū
Myasthenia gravis		7	0
Myasthenia gravis crisis		2	0
Olfactory nerve disorders		2	0
Anosmia		253	0
		233	0
Hyposmia			
Parosmia		236	0
Optic nerve disorders NEC			-
Optic neuritis		26	0
Paraesthesias and dysaesthe	esias	_	_
Burning feet syndrome		7	C
Burning sensation		504	C
Burning sensation mucosa		2	(
Dysaesthesia		7	(
Formication		39	(
Hand-arm vibration syndro	me	3	(
Hemianaesthesia		1	(
Hemiparaesthesia		3	C

Reaction Name		Total	Fatal
	Vervous system disorders cont'd		
Hyperaesthesia		88	0
Hypoaesthesia		2767	0
Paraesthesia		3797	0
Reversed hot-cold sensati	on	4	0
Synaesthesia		1	0
Paralysis and paresis (excl o	cranial nerve)		
Diplegia	·	12	0
Hemiparesis		47	0
Hemiplegia		37	0
Locked-in syndrome		1	0
Monoparesis		58	0
Monoplegia		75	0
Paralysis		123	0
Paraparesis		3	0
Paraplegia		2	0
Paresis		6	0
Quadriparesis		1	0
		1	0
Quadriplegia	rkingeniem	1	0
Parkinson's disease and par	(KIIISOIIISIII		0
Freezing phenomenon		8	0
Hypokinetic dysarthria		1	0
Parkinson's disease		3	0
Parkinsonian gait		1	0
Parkinsonian rest tremor		1	0
Parkinsonism		4	0
Reduced facial expression		11	0
Partial complex seizures			
Dreamy state		6	0
Focal dyscognitive seizure	es la	3	0
Temporal lobe epilepsy		2	0
Partial simple seizures NEC			
Autonomic seizure		1	0
Peripheral neuropathies NE	C		
Axonal neuropathy		2	0
Neuralgic amyotrophy		5	0
Neuritis		7	0
Neuropathy peripheral		112	0
Peripheral sensorimotor ne	europathy	1	0
Peripheral sensory neurop	bathy	12	0
Polyneuropathy	-	3	0
Thoracic outlet syndrome		1	0
Seizures and seizure disord	ers NEC		
Atonic seizures		5	0
Change in seizure present	ation	2	0
Clonic convulsion		3	0
Convulsions local		1	0
Epilepsy		153	0
Epileptic aura		2	0
Epileptic encephalopathy		1	0
Febrile convulsion		15	0
	0001	CI A	
Idiopathic generalised epil	еръу	1	0
Partial seizures		19	0
Post stroke seizure		1	0

Reaction Name		Total	Fatal
Nervous system disorders	Nervous system disorders cont'd		
Psychogenic seizure		8	0
Seizure		584	1
Seizure anoxic		2	0
Seizure cluster		6	0
Seizure like phenomena		2	0
Status epilepticus		44	0
Tonic clonic movements		3	0
Tonic convulsion		26	0
Tonic posturing		1	0
Sensory abnormalities NEC	•		
Ageusia		498	0
Allodynia		24	0
Aura		23	0
Complex regional pain syr	odrome	5	0
Dysgeusia		1103	
Electric shock sensation		36	0
Hypergeusia		1	0
Hypogeusia		7	0
Intercostal neuralgia		1	0
		2	
Loss of proprioception		3	0
Morton's neuralgia		500	0
Neuralgia	Providence and the second seco	506	0
Persistent genital arousal	disorder	1	0
Phantom limb syndrome		4	0
Post herpetic neuralgia		14	0
Restless arm syndrome		2	0
Restless legs syndrome		135	
Sensory disturbance		103	0
Sensory loss		73	
Taste disorder		245	0
Visual perseveration		3	0
Sleep disturbances NEC			
Sleep deficit		9	0
Sudden onset of sleep		1	0
Speech and language abno	rmalities		
Dysarthria		186	0
Incoherent		10	0
Language disorder		2	0
Repetitive speech		3	0
Slow speech		18	0
Speech disorder		66	0
Speech disorder developn	nental	1	0
Spinal cord and nerve root of	disorders NEC		
Cauda equina syndrome		1	0
Myelopathy		1	0
Radiculitis brachial		13	0
Radiculopathy		5	0
Structural brain disorders N	FC		
Brain injury		7	2
Cerebral ventricle dilatatio	n	1	Ć
Hyperintensity in brain dee		1	C
Transient cerebrovascular e			L
		111	3
Transient ischaemic attac	K	144	,

Reaction Name	Tota	ı	Fatal
	rvous system disorders cont'd		
Tremor (excl congenital)			
Essential tremor		5	0
Head titubation		13	0
Resting tremor		4	0
Tremor	16	30	0
Trigeminal disorders			
Numb chin syndrome		2	0
Trigeminal nerve disorder		3	0
Trigeminal neuralgia		59	0
Trigeminal neuritis		2	0
Vagus nerve disorders			
Vocal cord paralysis		2	0
Vertigos NEC			
Cervicogenic vertigo		1	0
Vertigo CNS origin		3	0
Nervous system disorders SOC	TOTAL 637	92	62

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortion related conditions and complications		
Anembryonic gestation	2	0
Abortions not specified as induced or spontaneous		
Abortion	1	0
Abortion missed	5	0
Abortions spontaneous		
Abortion spontaneous	374	0
Abortion threatened	2	0
Amniotic fluid and cavity disorders of pregnancy NEC		
Amniorrhoea	1	0
Foetal complications NEC		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	12	0
Foetal growth complications		
Foetal growth restriction	6	0
Gestational age and weight conditions		
Premature baby	4	1
Haemorrhagic complications of pregnancy		
Haemorrhage in pregnancy	2	0
Premature separation of placenta	3	0
Subchorionic haematoma	2	0
Subchorionic haemorrhage	1	0
Hypertension associated disorders of pregnancy		
Pre-eclampsia	1	0
Labour onset and length abnormalities		
Induced labour	1	0
Premature delivery	1	0
Premature labour	6	0
Premature rupture of membranes	3	0
Threatened labour	1	0
Maternal complications of delivery NEC		
Retained placenta or membranes	2	0
Maternal complications of labour NEC		
Uterine contractions abnormal	1	0
Uterine hypertonus	8	0
Maternal complications of pregnancy NEC		
Biochemical pregnancy	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	9	0
Hyperemesis gravidarum	1	0
Morning sickness	16	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
Newborn complications NEC		
Neonatal disorder	1	0
Normal newborn status		
Normal newborn	1	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	5	0

Reaction Name	Total	Fatal
Pregnancy conditions Pregnancy conditions cont'd		
Pregnancy	32	0
Uterine contractions during pregnancy	5	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	1	0
Placental disorder	1	0
Placental insufficiency	1	0
Postpartum complications NEC		
Postpartum haemorrhage	3	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	4	4
Stillbirth	7	7
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	2	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	556	12

Reaction Name	Total	Fatal
Device issues NEC		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
Device malfunction events NEC		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	15	0
Thrombosis in device	12	0
Device physical property and chemical issues		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	2	0
Product contamination and sterility issues		
Product contamination	11	0
Product contamination physical	6	0
Product packaging issues		
Product closure issue	1	0
Product physical issues		
Liquid product physical issue	9	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	2	0
Product physical issue	2	0
Product taste abnormal	10	0
Product quality issues NEC		
Product complaint	1	0
Product origin unknown	6	0
Product supply and availability issues		
Product availability issue	1	0
null SOC TOTAL	100	0

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	26	
Behaviour disorder	1	
Breath holding	6	
Staring	7	C
Adjustment disorders		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	C
Affect alterations NEC		
Affect lability	14	C
Constricted affect	3	C
Flat affect	11	C
Inappropriate affect	22	0
Amnestic symptoms		
Paramnesia	6	C
Anxiety disorders NEC		
Anxiety disorder	1	0
Generalised anxiety disorder	1	C
Neurosis	1	0
Anxiety symptoms		
Agitation	76	0
Anxiety	812	(
Immunisation anxiety related reaction	2	(
Nervousness	170	C
Stress	98	0
Tension	38	C
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	6	C
Behaviour and socialisation disturbances		
Aggression	14	C
Attention-seeking behaviour	1	0
Aversion	1	C
Disinhibition	2	0
Indifference	6	C
Paranoia	24	0
Personality change	4	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	(
Bipolar disorders		
Bipolar I disorder	2	(
Bipolar disorder	4	0
Cognitive and attention disorders and disturbances NEC		
Daydreaming	7	(
Distractibility	1	
Mental fatigue	201	(
Communications disorders		
Communication disorder	5	
Mutism	3	(
Confusion and disorientation		
Confusional state	846	(
Disorientation	275	
Decreased physical activity levels	270	

Reaction Name Psychiatric disorders cont'd	Total	Fatal
Catatonia	1	0
Deliria	110	0
Delirium Delizione (summatorne	110	0
Delusional symptoms	10	0
Delusion	13	0
Depressive disorders		0
Agitated depression	5	0
Depression	324	0
Depression suicidal	15	0
Major depression	10	0
Mixed anxiety and depressive disorder	3	0
Dissociative states		
Depersonalisation/derealisation disorder	11	0
Dissociation	30	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		-
Initial insomnia	23	0
Insomnia	1394	0
Middle insomnia	31	0
Terminal insomnia	32	0
Dyssomnias		-
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	210	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	10	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	36	0
Dysphoria	2	0
Emotional disorder	54	0
Emotional distress	43	0
Emotional poverty	1	0
Euphoric mood	43	0
Frustration tolerance decreased	2	0
Irritability	195	0
Mood altered	53	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Fear	19	0
Fear of death	1	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	C
Osmophobia	1	C
Phobia	3	C
Phonophobia	3	C
Social anxiety disorder	1	C
Social fear	1	0

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Fluctuating mood symptoms		
Mood swings	138	0
Hallucinations (excl sleep-related)		
Hallucination	197	0
Hallucination, auditory	15	0
Hallucination, olfactory	11	0
Hallucination, tactile	1	0
Hallucination, visual	25	0
Hallucinations, mixed	2	0
Increased physical activity levels		-
Restlessness	147	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		Ŭ
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		0
Mental disorder	15	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		0
Anhedonia	3	0
	9	
Decreased interest	-	0
Depressed mood	377	0
Depressive symptom		0
Feeling guilty		0
Feeling of despair	5	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	40	0
Mood alterations with manic symptoms		-
Hypomania	2	0
Mania	11	0
Mood disorders NEC		_
Affective disorder	3	0
Apathy	28	0
Boredom	1	0
Laziness	3	0
Listless	19	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Ănorgasmia	4	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0

Psychiatric disordersPsychiatric disorders cont'dPremature ejaculation1Panic attacks and disorders187Panic attack and disorders3Panic disorder3Panic disorder28Paraphilias and paraphilic disorders1Transvestism1Parasomnias1Abnormal dreams172Abnormal dreams1Confusional arousal1Exploding head syndrome2Nightmare188Parasomnia3Sleep terror21Somnambulism6Sleep terror21Somnambulism6Perception disturbances NEC17Autoscopy17Deja vu2Derealisation8Flashback3Illusion2Nightmare1Personality disorders NEC2Autoscopy17Deja vu2Derealisation8Flashback3Illusion2Personality disorders NEC2Personality disorders NEC2Personality disorder SEC2Personality disorder SEC2Psychiatic elimination disorders2Psychiatic symptoms NEC3Helplessness1Hypervigilance9Psychological trauma3Trance1Psychological trauma3Trance1Psychological trauma3Trance	atal
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Psychiatric symptom5Psychological trauma3Trance1Psychotic disorder NEC1	(
Psychological trauma3Trance1Psychotic disorder NEC1	(
Trance 1 Psychotic disorder NEC	(
Psychotic disorder NEC	(
	(
Acute psychosis	
	(
Psychotic behaviour 1	(
Psychotic disorder 23	(
Schizophrenia NEC	
Schizophrenia 1	(
Sexual and gender identity disorders NEC	
Gender dysphoria 1	(
Sexual arousal disorders	
Disturbance in sexual arousal 3	(
Sexual inhibition 1	(
Sexual desire disorders	
Hypersexuality 1	
Libido decreased 15 Libido increased 6	(

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Loss of libido	16	
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	
Sleep disorders NEC		
Sleep disorder	202	
Sleep disorder due to general medical condition, insomnia type	5	
Somatic symptom disorders		
Conversion disorder	21	
Habit cough	16	
Somatic symptom disorder	2	
Vomiting psychogenic	1	
Speech and language usage disturbances		
Disorganised speech	7	
Logorrhoea	2	
Speech articulation and rhythm disturbances		
Dysphemia	24	
Lack of spontaneous speech	1	
Pressure of speech	1	
Stereotypies and automatisms		
Automatism	1	
Bruxism	11	
Head banging	10	
Stereotypy	1	
Stress disorders		
Burnout syndrome	2	
Post-traumatic stress disorder	4	
Substance related and addictive disorders		
Alcohol problem	1	
Alcoholic hangover	1	
Alcoholism	3	
Nicotine dependence	2	
Suicidal and self-injurious behaviour		
Completed suicide	1	
Intentional self-injury	6	
Self-injurious ideation	2	
Suicidal ideation	39	
Suicide attempt	8	
Suicide threat	1	
Thinking disturbances		
Bradyphrenia	39	
Intrusive thoughts	7	
Morbid thoughts	1	
Tachyphrenia	5	
Thinking abnormal	19	
Thought blocking	19	
Tic disorders		
Tic	10	
sychiatric disorders SOC TOTAL	10 7731	

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort	2	C
Bladder irritation	8	
Bladder pain	28	C
Dysuria	47	C
Incontinence	26	C
Lower urinary tract symptoms	3	C
Micturition disorder	2	C
Micturition urgency	40	
Pollakiuria	126	
Stress urinary incontinence	1	C
Urethral pain	7	C
Urge incontinence	1	0
Urinary hesitation	2	C
Urinary incontinence	51	C
Urinary retention	38	C
Urine flow decreased	14	C
Bladder disorders NEC		
Bladder disorder	9	C
Bladder fibrosis	1	C
Bladder prolapse	1	C
Urinary bladder haemorrhage	2	C
Bladder infections and inflammations		
Cystitis interstitial	5	C
Cystitis noninfective	1	C
Genital and urinary tract disorders NEC		
Genitourinary symptom	1	C
Urinary tract disorder	4	C
Glomerulonephritis and nephrotic syndrome		
Glomerulonephritis minimal lesion	5	C
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	C
Nephrotic syndrome	17	0
Myoneurogenic bladder disorders		
Bladder dysfunction	5	C
Hypertonic bladder	1	C
Hypotonic urinary bladder	1	0
Loss of bladder sensation	2	C
Neurogenic bladder	2	C
Nephritis NEC		
Lupus nephritis	1	C
Nephritis	2	C
Tubulointerstitial nephritis	2	C
Nephropathies and tubular disorders NEC		
Nephropathy	1	C
Renal disorders NEC		
Renal disorder	5	1
Renal haemorrhage	1	0
Renal mass	1	0
Renal failure and impairment		
Acute kidney injury	47	4
Anuria	3	
Chronic kidney disease	4	

Reaction Name	Total	Fatal
Renal & urinary disorders Renal & urinary disorders cont'd		
Oliguria	1	C
Renal failure	20	1
Renal impairment	23	C
Renal injury	2	0
Renal lithiasis		
Nephrolithiasis	9	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	
Renal structural abnormalities and trauma		
Kidney small	1	0
Renal vascular and ischaemic conditions		
Renal aneurysm	1	C
Renal infarct	1	
Renal tubular necrosis	1	Ċ
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	C
Ureteric disorders NEC		
Ureteric stenosis	1	C
Urinary abnormalities		
Albuminuria	1	C
Chromaturia	47	C
Haematuria	35	
Ketonuria	1	
Myoglobinuria	1	
Proteinuria	11	
Urine abnormality	11	
Urine odour abnormal	8	
Urinary tract lithiasis (excl renal)		
Calculus urinary	1	C
Urinary tract signs and symptoms NEC	- ·	
Costovertebral angle tenderness	1	C
Cystitis-like symptom	1	
Haemorrhage urinary tract	21	
Nocturia	3	
	8	
Polyuria Renal colic		
	4	
Renal pain	267	
Urinary tract discomfort	1	(
Urinary tract pain	5	
Renal & urinary disorders SOC TOTAL	1018	7

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst	13	C
Breast disorders NEC		
Breast disorder	1	C
Breast enlargement	26	C
Breast mass	107	C
Gynaecomastia	4	C
Mastoptosis	1	C
Nipple disorder	1	C
Breast infections and inflammations		
Breast inflammation	3	C
Nipple inflammation	2	C
Breast signs and symptoms	_	,
Breast discharge	4	C
Breast discomfort	10	C
Breast engorgement	10	C
Breast haematoma	1	C
Breast oedema	5	C
	616	
Breast pain Breast swelling	138	0
5		
Breast tenderness	74	C
Nipple pain	37	1
Nipple swelling	4	C
Cervix disorders NEC		_
Cervical dysplasia	2	C
Cervix disorder	1	C
Cervix haemorrhage uterine	5	C
Ectropion of cervix	3	C
Cervix infections and inflammations		
Cervix inflammation	1	C
Cervix neoplasms		
Cervical polyp	1	C
Erection and ejaculation conditions and disorders		
Ejaculation disorder	2	C
Ejaculation failure	3	C
Erectile dysfunction	56	C
Erection increased	2	C
Organic erectile dysfunction	16	C
Painful ejaculation	1	C
Spontaneous ejaculation	1	C
Spontaneous penile erection	1	C
Fallopian tube and ovary infections and inflammations		,
Noninfective ophoritis	4	(
Lactation disorders		
Breast milk discolouration	3	(
Breast milk odour abnormal	2	(
Galactorrhoea	5	
Galactostasis	3	(
Lactation disorder	6	(
Lactation puerperal increased	5	(
Suppressed lactation	43	(
Menopausal effects NEC		
Artificial menopause	1	(

Reaction Name	Total	Fata
eproductive & breast disorders Reproductive & breast disorders cont'd		
Menopausal disorder	1	
Menopausal symptoms	25	
Menopause delayed	1	
Premature menopause	16	
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	1	
Postmenopausal haemorrhage	89	
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	6	
Abnormal withdrawal bleeding	1	
Dysmenorrhoea	2644	
Intermenstrual bleeding	1008	
Menstrual discomfort	26	
Menstrual disorder	1699	
Menstruation irregular	2978	
Premenstrual dysphoric disorder	11	
Premenstrual headache	10	
Premenstrual pain	112	
Premenstrual syndrome	103	
Retrograde menstruation	1	
Withdrawal bleed	15	
Menstruation with decreased bleeding		
Amenorrhoea	543	
Hypomenorrhoea	603	
Menstruation delayed	4538	
Oligomenorrhoea	147	
Menstruation with increased bleeding	147	
Heavy menstrual bleeding	5000	
Menometrorrhagia	17	
Polymenorrhoea	777	
Ovarian and fallopian tube cysts and neoplasms		
	1	
Haemorrhagic ovarian cyst	20	
Ovarian cyst	20	
Ovarian cyst ruptured	1	
Polycystic ovaries	43	
Ovarian and fallopian tube disorders NEC	1	
Adnexal torsion	1	
Hydrosalpinx	2	
Ovarian enlargement	1	
Ovarian haemorrhage	6	
Ovulation disorder	2	
Ovulation pain	61	
Premature ovulation	4	
Pelvic prolapse conditions		
Vaginal prolapse	1	
Pelvis and broad ligament disorders NEC		
Adnexa uteri mass	1	
Adnexa uteri pain	46	
Pelvic congestion	1	
Pelvic floor muscle weakness	1	
Pelvic haemorrhage	18	
Penile and scrotal infections and inflammations		
Balanoposthitis	2	

Reaction Name	Total	Fatal
eproductive & breast disorders Reproductive & breast disorders cont'd		
Penile disorders NEC (excl erection and ejaculation)		
Penile blister	1	
Penile discharge	1	
Penile discomfort	1	
Penile erythema	1	
Penile haemorrhage	3	
Penile pain	1	
Penile size reduced	1	
Penile swelling	5	
Penis disorder	9	
Prostate and seminal vesicles infections and inflammations		
Prostatitis	3	
Prostatic neoplasms and hypertrophy		
Benign prostatic hyperplasia	1	
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	1	
Prostatomegaly	3	
Reproductive tract disorders NEC (excl neoplasms)		
Genital erosion	1	
Genital haemorrhage	23	
Genital hypoaesthesia	1	
Genital lesion	2	
Genital paraesthesia	1	
Genital ulceration	6	
Perineal ulceration	1	
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	1	
Reproductive tract signs and symptoms NEC		
Genital burning sensation	2	
Genital erythema	1	
Genital pain	5	
Genital rash	4	
Genital swelling	3	
Pelvic discomfort	5	
Pelvic pain	96	
Perineal pain	2	
Perineal rash	1	
Pruritus genital	4	
Scrotal disorders NEC		
Acquired hydrocele	1	
Scrotal angiokeratoma	1	
Scrotal discomfort	1	
Scrotal erythema	1	
Scrotal exfoliation	1	
Scrotal pain	22	
Scrotal swelling	4	
Varicocele	1	
Sexual function and fertility disorders NEC		
Dyspareunia	6	
Infertility	9	
Infertility female	2	
Sexual dysfunction	6	
Spermatogenesis and semen disorders	0	

Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
Aspermia	1	(
Haematospermia	6	(
Semen discolouration	1	(
Testicular and epididymal disorders NEC		
Testicular disorder	3	(
Testicular pain	52	(
Testicular swelling	8	(
Testicular torsion	1	(
Testis discomfort	3	(
Uterine disorders NEC		
Adenomyosis	7	(
Endometrial thickening	4	(
Endometriosis	79	(
Uterine haemorrhage	35	(
Uterine pain	14	(
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	(
Uterine neoplasms		
Uterine polyp	4	(
Uterine tone disorders		
Uterine spasm	29	(
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	1	(
Vaginal cyst	6	(
Vaginal polyp	1	(
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1419	(
Vaginal mucosal blistering	1	(
Vaginal ulceration	1	(
Vulval disorder	1	(
Vulval haemorrhage	25	(
Vulval ulceration	7	(
Vulvovaginal ulceration	4	(
Vulvovaginal signs and symptoms		
Clitoral engorgement	1	(
Coital bleeding	5	(
Labia enlarged	1	(
Vaginal discharge	72	(
Vaginal lesion	1	(
Vaginal odour	2	(
Vulval oedema	1	(
Vulvovaginal burning sensation	4	(
Vulvovaginal dryness	5	(
Vulvovaginal erythema	1	(
Vulvovaginal pain	25	(
Vulvovaginal pruritus	8	
Vulvovaginal prontus Vulvovaginal rash	2	(
Vulvovaginal swelling	1	(
Reproductive & breast disorders SOC TOTAL	23897	

Reaction Name	<u> </u>	Fatal
Respiratory disorders		
Breathing abnormalities	-	
Apnoea	5	
Apnoeic attack	1	
Dyspnoea	4371	
Dyspnoea at rest	11	
Dyspnoea exertional	35	
Grunting	1	
Hyperventilation	48	
Hypopnoea	104	
Hypoventilation	1	
Irregular breathing	20	
Mouth breathing	5	
Nocturnal dysphoea	2	
Orthopnoea	3	
Respiration abnormal	52	
Respiratory arrest	14	
Respiratory depression	1	
Respiratory distress	17	
Sleep apnoea syndrome	12	
Tachypnoea	25	
Bronchial conditions NEC	20	
Bronchial secretion retention	4	
Bronchiectasis	12	
Bronchospasm and obstruction	12	
Asthma	224	
	334	
Asthma late onset	2	
Bronchospasm	15	
Chronic obstructive pulmonary disease	18	
Cough variant asthma	5	
Obstructive airways disorder	9	
Reversible airways obstruction	1	
Wheezing	377	
Conditions associated with abnormal gas exchange	_	
Asphyxia	2	
Cyanosis central	1	
Hyperoxia	1	
Нурохіа	28	
Respiratory acidosis	2	
Coughing and associated symptoms		
Allergic cough	7	
Cough	2308	
Cough decreased	2	
Haemoptysis	54	
Productive cough	157	
Sputum discoloured	7	
Sputum increased	3	
Diaphragmatic disorders	J	
Acquired diaphragmatic eventration	1	
Diaphragm muscle weakness	1	
Laryngeal and adjacent sites disorders NEC (excl infections and eoplasms)		
Laryngeal disorder	1	
Reflux laryngitis	1	

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Vocal cord disorder	1	0
Vocal cord dysfunction	2	0
Laryngeal spasm, oedema and obstruction		•
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	3	0
Laryngospasm	1	0
Stridor	23	0
Lower respiratory tract inflammatory and immunologic conditions Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	27	1
Pulmonary sarcoidosis	2	0
Lower respiratory tract signs and symptoms		
Hiccups	29	0
Increased bronchial secretion	2	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	1	0
Lung opacity	2	0
Pleuritic pain	21	0
Pulmonary haemorrhage	1	0
Pulmonary pain	85	0
Rales	5	0
Respiratory fremitus	1	0
Mediastinal disorders		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	267	0
Nasal inflammation	3	0
Rhinitis allergic	18	0
Nasal disorders NEC		
Epistaxis	847	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	35	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	6	0
Nasal polyps	1	0
Nasal pruritus	9	0
Neonatal hypoxic conditions		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	1	0
Paranasal sinus inflammation	3	0
Sinonasal obstruction	9	0
Sinus congestion	58	0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sinus disorder	6	0
Parenchymal lung disorders NEC		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	9	0
Lung consolidation	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	6	0
Pharyngeal disorders (excl infections and neoplasms)	5	J
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	7	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	35	0
Pharyngeal inflammation	33	0
Pharyngeal mass	4	0
	13	
Pharyngeal oedema	52	0 0
Pharyngeal paraesthesia		
Pharyngeal swelling	239	0
Pharyngeal ulceration	14	0
Tonsillar erythema	10	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	80	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
Pleural infections and inflammations		
Pleurisy	32	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	26	0
Pneumothorax	8	0
Pneumothorax spontaneous	3	0
Pulmonary hypertensions		
Pulmonary hypertension	2	0
Pulmonary oedemas		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	13	0
Pulmonary oedema	20	1
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	415	30
Pulmonary infarction	6	0
Pulmonary thrombosis	7	1
Respiratory failures (excl neonatal)		
Acute respiratory failure	2	1
Respiratory failure	11	2
Respiratory signs and symptoms NEC		
Allergic respiratory symptom	6	0
Diaphragmalgia	7	0
Nasal flaring	1	0

Reaction Name Respiratory disorders cont'd	Total	Fatal
Painful respiration	10	1
Pleural rub	10	0
Respiratory symptom	18	0
Suffocation feeling	2	0
Respiratory tract disorders NEC	2	0
Aspiration	2	0
Lung disorder	6	0
Pulmonary mass	4	0
Respiratory disorder	13	1
Respiratory tract congestion	3	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	3	Ő
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	2	0
Tracheal disorders (excl infections and neoplasms)	_	
Tracheal disorder	1	0
Tracheal pain	1	0
Upper respiratory tract neoplasms		
Tonsillar cyst	1	0
Upper respiratory tract signs and symptoms		
Aphonia	107	0
Catarrh	25	0
Choking	15	0
Choking sensation	3	0
Dry throat	163	0
Dysphonia	152	0
Increased upper airway secretion	5	0
Increased viscosity of upper respiratory secretion	31	0
Nasal discharge discolouration	3	0
Nasal discomfort	44	0
Nasal obstruction	2	0
Oropharyngeal blistering	10	0
Oropharyngeal discomfort	63	0
Oropharyngeal pain	2688	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	42	0
Rhinalgia	11	0
Rhinorrhoea	854	0
Sinus pain	197	0
Sneezing	352	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	218	0
Throat tightness	247	0
Upper airway obstruction	2	0
Upper respiratory tract congestion	2	C
Upper respiratory tract irritation	1	C
Upper-airway cough syndrome	9	C
Yawning	26	C
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	C

Reaction Name		Total	Fatal
Respiratory disorders	Respiratory disorders cont'd		
Respiratory disorders	SOC TOTAL	15998	51

Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	180	0
Acne cystic	20	(
Dermatitis acneiform	11	(
Alopecias		
Alopecia	262	(
Alopecia areata	40	
Alopecia totalis	2	
Androgenetic alopecia	2	(
Diffuse alopecia	4	
Hypotrichosis	1	(
Lichen planopilaris	1	(
Madarosis	4	
Angioedemas		
Angioedema	198	(
Circumoral swelling	100	
Apocrine and eccrine gland disorders		,
Anhidrosis	1	0
Bromhidrosis	1	
	724	
Cold sweat	124	(
Hidradenitis	4	
Hyperhidrosis	2066	
Hypohidrosis	2	(
Milia	2	(
Miliaria	85	(
Night sweats	575	(
Sweat discolouration	1	(
Bullous conditions		
Blister	427	(
Blister rupture	1	(
Blood blister	26	(
Dermatitis bullous	12	(
Erythema multiforme	36	(
Fracture blisters	1	(
Herpes gestationis	1	
Pemphigoid	23	
Pemphigus	7	(
Stevens-Johnson syndrome	5	
Toxic epidermal necrolysis	2	
Connective tissue disorders	_	
Cutaneous lupus erythematosus	1	(
Dermatomyositis	7	
Subacute cutaneous lupus erythematosus	1	
Dermal and epidermal conditions NEC		
Acute febrile neutrophilic dermatosis	1	(
Dermatosis	1	
	211	
Dry skin Koebber skonemenen	211	
Koebner phenomenon	1	
Macule	5	
Neutrophilic dermatosis	1	(
Pain of skin	250	
Papule	100	
Pathergy reaction	1	(

Skin disorders Skin disorders cont'd Scab		Fatal
	21	
Scar pain	13	
Sensitive skin	163	
Shagreen skin	100	
Skin burning sensation	201	
Skin degenerative disorder	201	
Skin discolouration	129	
Skin disconfort	129	
Skin disorder	26	
Skin fissures	8	
Skin indentation	0	
Skin induration	4	
Skin lesion	42	
Skin lesion inflammation	1	
Skin necrosis	2	
Skin odour abnormal	20	
Skin plaque	3	
Skin reaction	132	
Skin sensitisation	37	
Skin swelling	84	
Skin texture abnormal	2	
Skin tightness	26	
Skin warm	280	
Skin weeping	11	
Sticky skin	2	
Target skin lesion	2	
Transient acantholytic dermatosis	1	
Yellow skin	25	
Dermatitis and eczema		
Dermatitis	124	
Dermatitis allergic	220	
Dermatitis atopic	37	
Dermatitis contact	18	
Dermatitis diaper	3	
Dyshidrotic eczema	26	
Eczema	298	
Eczema asteatotic	9	
Eczema infantile	1	
Eczema nummular	5	
Eczema weeping	2	
Hand dermatitis	1	
Intertrigo	1	
Perioral dermatitis	2	
Seborrhoeic dermatitis	5	
Skin irritation	110	
Stasis dermatitis	1	
Dermatitis ascribed to specific agent		
Drug eruption	30	
Drug reaction with eosinophilia and systemic symptoms	1	
Fixed eruption	2	
Palmar-plantar erythrodysaesthesia syndrome	1	
Toxic skin eruption <i>Erythemas</i>	2	

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Erythema	2022	0
Palmar erythema	4	0
Red man syndrome	2	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	20	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	114	0
Granulomatous and deep cutaneous inflammatory conditions		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
Hyperkeratoses		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
Hyperpigmentation disorders		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	6	0
Solar lentigo	2	0
Hypertrichoses		
Hirsutism	2	0
Hypopigmentation disorders		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	18	0
Lipodystrophies		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	10	0
Nail disorder	2	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	8	0
Onychoclasis	5	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
Panniculitides		
Erythema nodosum	24	0
Panniculitis	1	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	16	0
Lichen sclerosus	9	0
Parapsoriasis	3	0
Pityriasis rosea	110	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	60	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pigmentation changes NEC		
Haemosiderin stain	1	
Pigmentation disorder	13	
Pilar disorders NEC		
Hair colour changes	10	
Hair disorder	1	
Hair growth abnormal	5	
Hair texture abnormal	6	
Piloerection	25	
Pseudofolliculitis	3	
Trichorrhexis	2	
Pruritus NEC		
Itching scar	5	
Pruritus	4968	
Psoriatic conditions		
Dermatitis psoriasiform	3	
Guttate psoriasis	14	
Nail psoriasis	1	
Palmoplantar pustulosis	2	
Psoriasis	172	
Pustular psoriasis	2	
Rebound psoriasis	1	
Purpura and related conditions		
Ecchymosis	1	
Henoch-Schonlein purpura	9	
Petechiae	140	
Purpura	52	
Pustular conditions		
Acute generalised exanthematous pustulosis	2	
Rashes, eruptions and exanthems NEC		
Butterfly rash	4	
Rash	5238	
Rash erythematous	1098	
Rash macular	470	
Rash maculo-papular	60	
Rash morbilliform	42	
Rash papular	319	
Rash pruritic	1101	
Rash vesicular	71	
Systemic lupus erythematosus rash	7	
Rosaceas		
Rosacea	28	
Scaly conditions		
Dandruff	4	
Pityriasis	22	
Sebaceous gland disorders		
Seborrhoea	10	
Skin and subcutaneous conditions NEC		
Cellulite	2	
Cutaneous symptom	5	
Reactive perforating collagenosis	1	
Skin mass	20	
Skin and subcutaneous tissue ulcerations	20	

Reaction Name Skin disorders cont'd	Total	Fatal
Skin disorders Skin disorders cont'd Ischaemic skin ulcer	4	
		0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	23	0
Skin ulcer	18	0
Skin cysts and polyps		
Dermal cyst	13	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	10	0
Skin haemorrhage	18	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin striae	7	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Needle track marks	4	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Skin oedema	4	0
Skin vasculitides		
Capillaritis	2	0
Cutaneous vasculitis	13	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	19	0
Skin vasomotor conditions		
Livedo reticularis	22	0
Telangiectasia and related conditions		Ű
Spider naevus	1	0
Telangiectasia	1	0
Urticarias		Ŭ
Chronic spontaneous urticaria	9	0
Cold urticaria	6	0
Idiopathic urticaria	1	0
Mechanical urticaria	8	0
Solar urticaria	2	0
Urticaria	1725	0
Urticaria cholinergic	1123	0
5	10	0
Urticaria chronic	19	
Urticaria contact	1	C
Urticaria papular	4	C
Urticaria thermal	6	C
Urticarial vasculitis	4	C
Skin disorders SOC TOTAL	25837	2

Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Infant	3	
Menarche	2	0
Menopause	37	
Postmenopause	3	(
Alcohol product use		
Alcoholic	1	(
Criminal activity		
Verbal abuse	1	0
Dependents		
Sick relative	5	(
Dietary and nutritional issues		
Feeding tube user	1	
Disability issues		
Bedridden	25	
Blood product transfusion dependent	1	
Breast prosthesis user	3	
Disability	2	
Hearing disability	1	
Housebound	1	
Immobile	13	
Impaired driving ability	4	
Impaired work ability	12	
Loss of personal independence in daily activities	38	
	5	
Physical disability	10	
Sight disability		
Sitting disability	3	
Walking disability	1	(
Wheelchair user	1 1	(
Economic circumstances		
High income	1	(
Low income	1	0
Educational issues		
Educational problem	1	(
Illiteracy	1	0
Employment issues		
Job dissatisfaction	1	(
Retirement	4	0
Stress at work	2	(
Family and partner issues		
Bed sharing	1	(
Non-occupational and unspecified environmental problems		
Flooding	1	(
Water pollution	2	0
Pregnancy related circumstances		
Breast feeding	15	(
Multigravida	1	(
Parity	1	
Social issues NEC		
Exercise adequate	1	
Hair dye user	2	
Impaired quality of life	3	
Tobacco use	3	

Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Ex-tobacco user	1	0
Non-tobacco user	3	0
Tobacco user	1	0
Social circumstances SOC TOTAL	216	0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Anaesthesia and allied procedures		
Local anaesthesia	2	C
Nerve block	4	C
Analgesia supportive care		
Analgesic therapy	1	C
Antiinfective therapies		
COVID-19 prophylaxis	1	C
COVID-19 treatment	4	C
Arterial therapeutic procedures (excl aortic)		
Splenic artery embolisation	1	C
Blood and blood product treatment		
Transfusion	2	(
Breast therapeutic procedures NEC		
Axillary lymphadenectomy	3	(
Mammoplasty	1	C
Bronchial and pulmonary therapeutic procedures		
Airway secretion clearance therapy	1	C
Cardiac device therapeutic procedures		
Cardiac pacemaker insertion	1	C
Cardiac therapeutic procedures NEC		
Cardiac operation	1	0
Contraceptive methods female		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	C
Contraceptive methods male		
Condom	1	0
Dietary and nutritional therapies		
Medical diet	8	C
Nothing by mouth order	9	C
Wheat-free diet	1	C
External ear therapeutic procedures		
Ear irrigation	1	C
Fertility and fertilisation interventions female		
Endometrial scratching	1	C
Gastrointestinal therapeutic procedures NEC		
Intestinal anastomosis	1	C
Prophylaxis of nausea and vomiting	16	C
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	13	C
Haematological therapeutic procedures NEC		
Anticoagulant therapy	1	(
Head, neck and oral cavity therapeutic procedures NEC		
Neck lift	1	(
Hernia repairs		
Hernia repair	1	(
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	1	(
Hormone therapy	8	(
Immunisations		
COVID-19 immunisation	95	(
Immunisation	102	
Influenza immunisation	2	(

Reaction Name Surgical & medical procedures Surgical & medical procedures cont'd	Total	Fatal
Smallpox immunisation	1	0
Induced abortions		U
Abortion induced	2	0
Joint therapeutic procedures	2	0
Joint injection	3	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		0
Appendicectomy	4	0
Limb therapeutic procedures	4	0
Arm amputation	1	0
Limb immobilisation	9	0
Limb operation	6	0
Lymphoid tissue therapeutic procedures	Ŭ	0
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		0
Breast conserving surgery	4	0
Nail therapeutic procedures		Ū
Nail operation	3	0
Nervous system therapeutic procedures NEC	Ŭ	Ŭ
Multiple sclerosis relapse prophylaxis	2	0
Obstetric therapeutic procedures	_	Ŭ
Caesarean section	1	0
Labour stimulation	1	0
Orbit and globe therapeutic procedures		Ŭ
Strabismus correction	1	0
Ovarian therapeutic procedures		Ŭ
Ovarian operation	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		-
UV light therapy	1	0
Prophylactic procedures NEC		-
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	3	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	5	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0

	Total	Fatal
Surgical & medical procedures Surgical & medical procedures cont'd		
Small intestine therapeutic procedures		•
lleostomy	1	0
Therapeutic bladder catheterisation		-
Bladder catheterisation	2	0
Therapeutic procedures NEC		•
Abscess drainage	1	0
Anaphylaxis treatment	6	0
Bed rest	3	0
Fatigue management	1	0
Hospitalisation	11	0
Injection	50	0
Interchange of vaccine products	29	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	2	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	3	0
Vascular therapeutic procedures NEC		
Angioplasty	1	0
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	481	1

Reaction Name	Total	Fatal
ascular disorders		
Accelerated and malignant hypertension		
Hypertensive crisis	11	
Hypertensive urgency	1	
Malignant hypertension	4	
Aneurysms and dissections non-site specific		
Aneurysm	2	
Artery dissection	2	
Aortic aneurysms and dissections		
Acute aortic syndrome	1	
Aortic aneurysm rupture	1	
Aortic dissection	1	
Aortic embolism and thrombosis		
Aortic embolus	5	
Aortic thrombosis	2	
Aortic necrosis and vascular insufficiency		
Aortic occlusion	1	
Arterial infections and inflammations		
Arteritis	1	
Giant cell arteritis	12	
Blood pressure disorders NEC		
Blood pressure fluctuation	10	
Labile blood pressure	3	
Bruising, ecchymosis and purpura	J J	
Achenbach syndrome	3	
Circulatory collapse and shock	Ŭ	
CT hypotension complex	2	
Circulatory collapse	66	
Hypoperfusion	2	
Hypovolaemic shock	1	
	21	
Neurogenic shock		
Peripheral circulatory failure	6 19	
Shock	19	
Haemorrhages NEC		
Arterial haemorrhage	1	
Bloody discharge	23	
Haematoma	46	
Haemorrhage	1138	
Internal haemorrhage	8	
Venous haemorrhage	2	
Lymphangiopathies		
Lymphangiopathy	1	
Lymphocele	4	
Lymphoedemas		
Lymphoedema	196	
Non-site specific embolism and thrombosis		
Arterial thrombosis	4	
Embolism	60	
Embolism venous	6	
Microembolism	1	
Thrombosis	393	
Venous thrombosis	7	
Non-site specific necrosis and vascular insufficiency NEC		
Arterial occlusive disease	2	

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Arterial spasm	1	0
Arteriosclerosis	2	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	10	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
Non-site specific vascular disorders NEC		
Capillary disorder	1	0
Capillary fragility	1	0
Superficial vein prominence	1	0
Vascular pain	31	0
Vascular wall hypertrophy	1	0
Vasodilatation	35	
Vein discolouration	5	0
Vein disorder	6	
Vein rupture	5	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	1	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0
Blue toe syndrome	25	
Deep vein thrombosis	265	
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	1	0
Peripheral embolism	1	0
Subclavian artery embolism	1	0
Subclavian vein thrombosis	3	0
Superficial vein thrombosis	17	0
Thrombophlebitis	22	0
Peripheral vascular disorders NEC		
Cyanosis	41	0
Erythromelalgia	2	0
Flushing	400	0
Hot flush	1081	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	1	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	307	0
Peripheral ischaemia	12	0
Poor peripheral circulation	16	0
Raynaud's phenomenon	53	0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	31	0
Phlebitis superficial	7	0
Site specific vascular disorders NEC		
Aortic dilatation	1	0
Inferior vena cava dilatation	1	0
Pallor	357	0
Varicose veins NEC		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	30	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	3	0
Essential hypertension	3	0
Hypertension	549	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	6	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Diastolic hypotension	1	0
Hypotension	374	1
Orthostatic hypotension	30	0
Vasculitides NEC		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	46	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	5915	15
TOTAL REACTIONS FOR DRUG	370739	611
TOTAL REPORTS	130924	
TOTAL FATAL OUTCOME REPORTS		611