

## COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022  
Data Lock Date: 12-Jan-2022 18:30:17

All UK spontaneous reports received between 04/01/21 and 12/01/22 for COVID-19 vaccine Oxford University/AstraZeneca

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.

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemia deficiencies</i></b>		
Anaemia folate deficiency	3	0
Anaemia vitamin B12 deficiency	15	0
Deficiency anaemia	1	0
Iron deficiency anaemia	17	0
Pernicious anaemia	6	0
<b><i>Anaemias NEC</i></b>		
Anaemia	188	0
Autoimmune anaemia	2	0
Blood loss anaemia	4	0
Hypochromic anaemia	3	0
Microcytic anaemia	1	0
Normocytic anaemia	4	0
<b><i>Anaemias haemolytic NEC</i></b>		
Haemolytic anaemia	9	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	10	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
<b><i>Anaemias haemolytic mechanical factor</i></b>		
Atypical haemolytic uraemic syndrome	1	0
Red cell fragmentation syndrome	1	0
<b><i>Bleeding tendencies</i></b>		
Increased tendency to bruise	141	0
Spontaneous haematoma	8	0
Spontaneous haemorrhage	2	0
<b><i>Coagulation factor deficiencies</i></b>		
Acquired haemophilia	1	0
Hypofibrinogenaemia	4	0
<b><i>Coagulopathies</i></b>		
Abnormal clotting factor	12	0
Antiphospholipid syndrome	30	0
Coagulopathy	86	0
Disseminated intravascular coagulation	19	2
Hypercoagulation	25	1
Hyperfibrinogenaemia	1	0
Hypocoagulable state	1	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	22	0
Hypereosinophilic syndrome	1	0
<b><i>Haematological cysts and polyps</i></b>		
Splenic cyst	1	0
<b><i>Haematological disorders</i></b>		
Blood disorder	15	1
Bone marrow disorder	3	0
Bone marrow oedema	1	0
Mast cell activation syndrome	12	0
Mastocytosis	3	0
Methaemoglobinaemia	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	11	0
<b><i>Leukocytoses NEC</i></b>		
Leukocytosis	4	0

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<b>Blood disorders</b> Blood disorders cont'd		
Lymphocytosis	11	0
Monocytosis	2	0
Neutrophilia	14	0
<b>Leukopenias NEC</b>		
Leukopenia	15	0
Lymphopenia	9	0
<b>Lymphatic system disorders NEC</b>		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	1	0
Lymph node fibrosis	1	0
Lymph node pain	592	0
Lymphadenitis	33	0
Lymphadenopathy	5002	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	2	0
Lymphatic insufficiency	1	0
Lymphoid tissue hyperplasia	1	0
Pseudolymphoma	4	0
<b>Marrow depression and hypoplastic anaemias</b>		
Aplastic anaemia	6	0
Cytopenia	1	0
Myelosuppression	5	0
Pancytopenia	19	1
<b>Neutropenias</b>		
Agranulocytosis	4	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	83	0
<b>Platelet disorders NEC</b>		
Platelet anisocytosis	4	0
Platelet disorder	8	0
<b>Polycythaemia (excl rubra vera)</b>		
Polycythaemia	3	0
Stress polycythaemia	3	0
<b>Purpuras (excl thrombocytopenic)</b>		
Purpura non-thrombocytopenic	4	0
<b>Red blood cell abnormal findings NEC</b>		
Anisocytosis	3	0
Macrocytosis	3	0
Poikilocytosis	1	0
Polychromasia	4	0
Red blood cell abnormality	1	0
Rouleaux formation	1	0
<b>Sickle cell trait and disorders</b>		
Sickle cell anaemia with crisis	6	0
<b>Spleen disorders</b>		
Spleen disorder	1	0
Splenic artery thrombosis	3	0
Splenic haemorrhage	1	0
Splenic infarction	17	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	13	0

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<b>Blood disorders</b> Blood disorders cont'd		
Splenomegaly	7	0
Spleno renal shunt	1	0
<b><i>Thrombocytopenias</i></b>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	14	0
Immune thrombocytopenia	218	1
Thrombocytopenia	892	7
Thrombocytopenic purpura	11	0
Thrombosis with thrombocytopenia syndrome	12	0
Thrombotic thrombocytopenic purpura	11	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	12	0
<b><i>White blood cell abnormal findings NEC</i></b>		
White blood cell disorder	4	0
<b>Blood disorders SOC TOTAL</b>	<b>7743</b>	<b>13</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Aortic valvular disorders</b></i>		
Aortic valve incompetence	4	0
Aortic valve sclerosis	1	0
Aortic valve stenosis	1	0
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	32	1
Atrioventricular block complete	3	0
Atrioventricular block first degree	3	0
Atrioventricular block second degree	5	0
Bundle branch block	2	0
Bundle branch block left	10	0
Bundle branch block right	4	0
Long QT syndrome	1	0
Trifascicular block	2	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	4	2
Atrial thrombosis	5	0
Cardiac disorder	89	2
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	12	2
Cardiovascular disorder	10	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	19	2
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	2	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	2	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	19	0
Cardiovascular symptom	3	0
Palpitations	5769	0
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	4	1
Heart valve incompetence	4	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	17	1
Cardiomyopathy acute	1	0
Congestive cardiomyopathy	12	1
Stress cardiomyopathy	5	0
<i><b>Coronary artery disorders NEC</b></i>		
Arteriosclerosis coronary artery	7	1
Coronary artery disease	10	0
Coronary artery dissection	5	1
Coronary artery embolism	1	0
Coronary artery occlusion	4	0
Coronary artery stenosis	1	0
Coronary artery thrombosis	24	3
<i><b>Heart failure signs and symptoms</b></i>		
Cardiac asthma	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	106	13
Cardiac failure acute	13	4
Cardiac failure chronic	2	1

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Cardiac failure congestive	7	3
Cardiogenic shock	11	2
Cardiopulmonary failure	1	1
Ventricular failure	1	0
<b>Ischaemic coronary artery disorders</b>		
Acute coronary syndrome	9	0
Acute myocardial infarction	89	14
Angina pectoris	256	0
Angina unstable	18	0
Arteriospasm coronary	7	0
Microvascular coronary artery disease	2	0
Myocardial infarction	468	55
Myocardial ischaemia	28	12
Prinzmetal angina	2	0
<b>Left ventricular failures</b>		
Acute left ventricular failure	2	0
Left ventricular failure	10	1
<b>Mitral valvular disorders</b>		
Ischaemic mitral regurgitation	1	0
Mitral valve disease	1	0
Mitral valve incompetence	10	0
Mitral valve prolapse	4	0
<b>Myocardial disorders NEC</b>		
Cardiac aneurysm	1	0
Cardiac sarcoidosis	1	0
Cardiomegaly	35	1
Diastolic dysfunction	2	0
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	23	0
Left ventricular hypertrophy	4	0
Myocardial fibrosis	2	0
Myocardial injury	14	0
Myocardial oedema	1	0
Myocardial rupture	1	0
Right atrial dilatation	2	0
Right ventricular dilatation	3	0
Right ventricular dysfunction	4	0
Systolic dysfunction	1	0
Ventricular dyskinesia	1	0
Ventricular hypertrophy	5	1
Ventricular hypokinesia	3	0
<b>Noninfectious myocarditis</b>		
Autoimmune myocarditis	1	0
Myocarditis	207	3
Myocarditis post infection	1	0
<b>Noninfectious pericarditis</b>		
Pericarditis	208	0
<b>Pericardial disorders NEC</b>		
Cardiac tamponade	2	2
Pericardial disease	1	0
Pericardial effusion	38	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Pericardial haemorrhage	8	4
Pericardial rub	2	0
<b><i>Rate and rhythm disorders NEC</i></b>		
Arrhythmia	158	3
Arrhythmia neonatal	1	0
Bradyarrhythmia	1	0
Bradycardia	88	0
Brugada syndrome	1	0
Cardiac fibrillation	9	0
Cardiac flutter	300	0
Extrasystoles	164	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	26	0
Tachyarrhythmia	11	0
Tachycardia	1559	0
<b><i>Right ventricular failures</i></b>		
Right ventricular failure	4	1
<b><i>Supraventricular arrhythmias</i></b>		
Arrhythmia supraventricular	17	0
Atrial fibrillation	345	1
Atrial flutter	51	0
Atrial tachycardia	3	0
Sinus arrest	1	0
Sinus arrhythmia	3	0
Sinus bradycardia	5	0
Sinus node dysfunction	2	0
Sinus tachycardia	71	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	44	0
<b><i>Tricuspid valvular disorders</i></b>		
Tricuspid valve incompetence	8	0
<b><i>Ventricular arrhythmias and cardiac arrest</i></b>		
Cardiac arrest	182	37
Cardio-respiratory arrest	2	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	2	0
Ventricular extrasystoles	23	0
Ventricular fibrillation	10	1
Ventricular tachycardia	17	0
<b>Cardiac disorders SOC TOTAL</b>	<b>10855</b>	<b>178</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Autosomal chromosomal abnormalities</b></i>		
Trisomy 18	1	0
Trisomy 21	1	0
<i><b>Cardiac disorders congenital NEC</b></i>		
Heart disease congenital	11	0
<i><b>Cardiac septal defects congenital</b></i>		
Atrial septal defect	1	0
Hypertrophic cardiomyopathy	3	0
<i><b>Central nervous system disorders congenital NEC</b></i>		
Brain malformation	1	0
Neural tube defect	1	1
Spina bifida	2	0
Syringomyelia	1	0
<i><b>Cerebellar disorders congenital</b></i>		
Arnold-Chiari malformation	2	0
<i><b>Cerebral disorders congenital</b></i>		
Anencephaly	1	0
Cerebral palsy	2	0
<i><b>Coagulation disorders congenital</b></i>		
Factor VII deficiency	1	0
<i><b>Congenital disorders NEC</b></i>		
Congenital anomaly	4	0
Congenital midline defect	1	0
Heterotaxia	1	0
Multiple congenital abnormalities	1	0
Young's syndrome	1	0
<i><b>Connective tissue disorders congenital</b></i>		
Ehlers-Danlos syndrome	6	0
<i><b>Diaphragmatic disorders congenital</b></i>		
Congenital diaphragmatic hernia	2	0
<i><b>Gastrointestinal tract disorders congenital NEC</b></i>		
Gastrointestinal malformation	1	0
<i><b>Gene mutations and other alterations NEC</b></i>		
Tuberous sclerosis complex	1	0
<i><b>Great vessel disorders congenital</b></i>		
Coarctation of the aorta	1	0
Transposition of the great vessels	1	0
<i><b>Immune system abnormalities congenital</b></i>		
Combined immunodeficiency	1	0
<i><b>Inborn errors of lipid metabolism</b></i>		
Type IIa hyperlipidaemia	1	0
<i><b>Inborn errors of porphyrin metabolism</b></i>		
Porphyria acute	1	0
<i><b>Lacrimal system disorders congenital</b></i>		
Dacryostenosis congenital	1	0
<i><b>Lysosomal storage disorders</b></i>		
Mucopolipidosis	1	0
<i><b>Male reproductive tract disorders congenital</b></i>		
Hydrocele	2	0
Micropenis	2	0
Penoscrotal fusion	3	0
<i><b>Multiple cardiac abnormalities congenital</b></i>		
Multiple cardiac defects	1	0

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Reaction Name	Total	Fatal
<b>Congenital disorders</b> Congenital disorders cont'd		
<b><i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i></b>		
Branchial cyst	3	0
<b><i>Musculoskeletal and connective tissue disorders of limbs congenital</i></b>		
Limb reduction defect	2	0
Os trigonum	1	0
<b><i>Musculoskeletal disorders congenital NEC</i></b>		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	2	0
<b><i>Neurological disorders congenital NEC</i></b>		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Neurofibromatosis	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	3	0
<b><i>Ocular disorders congenital NEC</i></b>		
Colour blindness	9	0
<b><i>Pancreatic disorders congenital</i></b>		
Hereditary pancreatitis	1	0
<b><i>Peripheral nervous system disorders congenital NEC</i></b>		
Paroxysmal extreme pain disorder	13	0
<b><i>Pulmonary and bronchial disorders congenital</i></b>		
Cystic fibrosis	1	0
<b><i>Sex chromosomal abnormalities</i></b>		
Klinefelter's syndrome	1	0
<b><i>Skin and subcutaneous tissue disorders congenital NEC</i></b>		
Benign familial pemphigus	1	0
<b><i>Tongue disorders congenital</i></b>		
Ankyloglossia congenital	1	0
Macroglossia	1	0
<b><i>Vascular anomalies congenital NEC</i></b>		
Arteriovenous malformation	1	0
Vascular malformation	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>107</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Aural polyp	1	0
Ear canal erythema	1	0
Ear congestion	34	0
Ear discomfort	123	0
Ear disorder	23	0
Ear haemorrhage	19	0
Ear inflammation	1	0
Ear pain	2097	0
Ear pruritus	7	0
Ear swelling	75	0
Otorrhoea	8	0
Paraesthesia ear	1	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	7	0
Eustachian tube dysfunction	6	0
Eustachian tube obstruction	8	0
<i><b>External ear disorders NEC</b></i>		
Excessive cerumen production	41	0
External ear pain	14	0
Juvenile spring eruption	1	0
Red ear syndrome	5	0
<i><b>External ear infections and inflammations</b></i>		
External ear inflammation	4	0
<i><b>Hearing disorders NEC</b></i>		
Auditory disorder	8	0
<i><b>Hearing losses</b></i>		
Conductive deafness	1	0
Deafness	418	1
Deafness bilateral	19	0
Deafness neurosensory	40	0
Deafness transitory	4	0
Deafness unilateral	58	0
Hypoacusis	250	0
Mixed deafness	3	0
Neurosensory hypoacusis	2	0
Sudden hearing loss	84	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	176	0
<i><b>Inner ear disorders NEC</b></i>		
Endolymphatic hydrops	1	0
Inner ear disorder	8	0
Meniere's disease	30	0
Vestibular disorder	9	0
<i><b>Inner ear infections and inflammations</b></i>		
Autoimmune inner ear disease	1	0
Inner ear inflammation	5	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	130	0
Phobic postural vertigo	2	0
Tinnitus	4357	0
Vertigo	2293	0
Vertigo labyrinthine	14	0

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<b>Ear disorders</b> Ear disorders cont'd		
Vertigo positional	158	0
<b>Middle ear disorders NEC</b>		
Middle ear disorder	1	0
Middle ear effusion	6	0
<b>Tympanic membrane disorders (excl infections)</b>		
Tympanic membrane perforation	7	0
<b>Ear disorders SOC TOTAL</b>	<b>10561</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<b><i>Acute and chronic thyroiditis</i></b>		
Autoimmune thyroiditis	8	0
Thyroiditis	21	0
Thyroiditis acute	8	0
Thyroiditis chronic	2	0
Thyroiditis subacute	8	0
<b><i>Adrenal cortical hyperfunctions</i></b>		
Cushing's syndrome	2	0
Cushingoid	5	0
<b><i>Adrenal cortical hypofunctions</i></b>		
Addison's disease	3	0
Adrenal insufficiency	22	0
Adrenocortical insufficiency acute	31	0
Glucocorticoid deficiency	1	0
<b><i>Adrenal gland disorders NEC</i></b>		
Adrenal disorder	2	0
Adrenal haematoma	1	0
Adrenal haemorrhage	7	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
Adrenomegaly	2	0
Haemorrhagic adrenal infarction	5	0
<b><i>Anterior pituitary hyperfunction</i></b>		
Hyperprolactinaemia	2	0
<b><i>Anterior pituitary hypofunction</i></b>		
Hypopituitarism	2	0
Luteal phase deficiency	2	0
<b><i>Ectopic endocrine disorders</i></b>		
Carcinoid syndrome	1	0
<b><i>Endocrine abnormalities of gonadal function NEC</i></b>		
Oestrogenic effect	1	0
<b><i>Endocrine abnormalities of puberty</i></b>		
Delayed menarche	2	0
Premature menarche	17	0
<b><i>Female gonadal function disorders</i></b>		
Anovulatory cycle	23	0
Ovulation delayed	18	0
<b><i>Hyperparathyroid disorders</i></b>		
Hyperparathyroidism	2	0
<b><i>Hypoparathyroid disorders</i></b>		
Hypoparathyroidism	2	0
Primary hypoparathyroidism	1	0
<b><i>Hypothalamic and pituitary disorders NEC</i></b>		
Empty sella syndrome	1	0
Hypothalamo-pituitary disorder	2	0
Pituitary apoplexy	2	0
Pituitary haemorrhage	1	0
Secondary adrenocortical insufficiency	1	0
<b><i>Posterior pituitary disorders</i></b>		
Diabetes insipidus	8	0
Inappropriate antidiuretic hormone secretion	1	0
<b><i>Thyroid disorders NEC</i></b>		
Autoimmune thyroid disorder	1	0

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<b>Endocrine disorders</b> Endocrine disorders cont'd		
Euthyroid sick syndrome	1	0
Goitre	27	0
Thyroid disorder	21	0
Thyroid mass	8	0
Thyroid pain	18	0
<b><i>Thyroid hyperfunction disorders</i></b>		
Basedow's disease	23	0
Hyperthyroidism	63	0
Thyrotoxic crisis	6	0
<b><i>Thyroid hypofunction disorders</i></b>		
Hypothyroidism	64	0
<b><i>Thyroid neoplasms</i></b>		
Thyroid cyst	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>452</b>	<b>0</b>

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<b>Eye disorders</b>		
<b><i>Amblyopic vision impairment</i></b>		
Amblyopia	12	0
<b><i>Cataract conditions</i></b>		
Cataract	25	0
Cataract cortical	2	0
Cataract subcapsular	4	0
<b><i>Choroid and vitreous haemorrhages and vascular disorders</i></b>		
Vitreous haematoma	1	0
Vitreous haemorrhage	9	0
<b><i>Choroid and vitreous structural change, deposit and degeneration</i></b>		
Chorioretinopathy	2	0
Vitreous detachment	59	0
Vitreous floaters	206	0
Vitreous opacities	1	0
<b><i>Colour blindness (incl acquired)</i></b>		
Dyschromatopsia	18	0
<b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>		
Conjunctival haemorrhage	130	0
Corneal neovascularisation	1	0
Scleral haemorrhage	1	0
<b><i>Conjunctival infections, irritations and inflammations</i></b>		
Conjunctival hyperaemia	2	0
Conjunctivitis allergic	2	0
<b><i>Conjunctival structural change, deposit and degeneration</i></b>		
Conjunctival bleb	1	0
Conjunctival disorder	1	0
<b><i>Corneal infections, oedemas and inflammations</i></b>		
Keratitis	5	0
Ulcerative keratitis	4	0
<b><i>Corneal structural change, deposit and degeneration</i></b>		
Corneal perforation	1	0
Corneal scar	1	0
<b><i>Eyelid movement disorders</i></b>		
Blepharospasm	157	0
Excessive eye blinking	8	0
Eyelid function disorder	1	0
Eyelid myokymia	2	0
Eyelid ptosis	64	0
Paralytic lagophthalmos	1	0
<b><i>Glaucomas (excl congenital)</i></b>		
Angle closure glaucoma	6	0
Glaucoma	16	0
<b><i>Iris and ciliary body structural change, deposit and degeneration</i></b>		
Eye colour change	9	0
<b><i>Iris and uveal tract infections, irritations and inflammations</i></b>		
Autoimmune uveitis	1	0
Iridocyclitis	25	0
Iritis	15	0
Uveitis	54	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	322	0
Lacrimation increased	263	0
<b><i>Lens structural change, deposit and degeneration (excl cataracts)</i></b>		

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Anterior capsule contraction	1	0
<b>Lid bleeding and vascular disorders</b>		
Eyelid bleeding	3	0
Eyelid haematoma	3	0
<b>Lid, lash and lacrimal infections, irritations and inflammations</b>		
Blepharitis	30	0
Chalazion	2	0
Eczema eyelids	7	0
Erythema of eyelid	8	0
Eyelid cyst	18	0
Eyelid irritation	5	0
Eyelid margin crusting	1	0
Eyelid oedema	12	0
Eyelid rash	15	0
Meibomianitis	1	0
Swelling of eyelid	139	0
<b>Lid, lash and lacrimal structural disorders</b>		
Blepharal pigmentation	1	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	6	0
Eyelid thickening	4	0
Growth of eyelashes	10	0
Lagophthalmos	4	0
<b>Ocular bleeding and vascular disorders NEC</b>		
Eye haematoma	4	0
Eye haemorrhage	114	0
Ocular retrobulbar haemorrhage	1	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	4	0
<b>Ocular cysts and polyps</b>		
Vitreous cyst	1	0
<b>Ocular disorders NEC</b>		
Dark circles under eyes	11	0
Eye disorder	46	0
Eye oedema	19	0
Eye pain	3383	0
Eye swelling	640	0
Eye symptom	11	0
Eye ulcer	10	0
Eyelid disorder	18	0
Eyelid pain	20	0
Eyelids pruritus	13	0
Ocular discomfort	83	0
Periorbital discomfort	1	0
Periorbital oedema	18	0
Periorbital pain	4	0
Periorbital swelling	109	0
Retinal disorder	2	0
Retinal fovea disorder	1	0
<b>Ocular infections, inflammations and associated manifestations</b>		
Autoimmune eye disorder	1	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Eye allergy	31	0
Eye discharge	29	0
Eye inflammation	35	0
Eye irritation	206	0
Eye pruritus	309	0
Limbal swelling	8	0
Ocular hyperaemia	472	0
Ocular rosacea	1	0
<b>Ocular nerve and muscle disorders</b>		
Extraocular muscle paresis	13	0
Eye movement disorder	56	0
Gaze palsy	5	0
Ocular myasthenia	4	0
Ophthalmoplegia	2	0
Parinaud syndrome	1	0
Strabismus	5	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	28	0
Asthenopia	363	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	37	0
Hypoaesthesia eye	29	0
Photophobia	1086	0
<b>Optic disc abnormalities NEC</b>		
Optic atrophy	1	0
Optic discs blurred	3	0
Papilloedema	16	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic disc haemorrhage	2	0
Optic ischaemic neuropathy	11	0
Optic nerve sheath haemorrhage	1	0
<b>Orbital infections, inflammations and irritations</b>		
Orbital myositis	1	0
Parophthalmia	1	0
<b>Orbital structural change, deposit and degeneration</b>		
Lid sulcus deepened	3	0
Orbital oedema	1	0
<b>Pupil disorders</b>		
Holmes-Adie pupil	1	0
Miosis	15	0
Mydriasis	35	0
Pupil fixed	14	0
Pupillary deformity	1	0
Pupillary reflex impaired	3	0
Pupils unequal	12	0
<b>Refractive and accommodative disorders</b>		
Altered visual depth perception	5	0
Hypermetropia	3	0
Myopia	5	0
Refraction disorder	1	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Retinal aneurysm	2	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Retinal artery embolism	5	0
Retinal artery occlusion	26	0
Retinal haemorrhage	20	0
Retinal infarction	1	0
Retinal ischaemia	2	0
Retinal vascular occlusion	3	0
Retinal vascular thrombosis	4	0
Retinal vein occlusion	99	0
Retinal vein thrombosis	8	0
Retinal vein varices	1	0
Retinal vessel avulsion	1	0
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Epiretinal membrane	1	0
Macular cyst	1	0
Macular degeneration	9	0
Macular detachment	1	0
Macular hole	2	0
Macular rupture	2	0
Maculopathy	3	0
Neovascular age-related macular degeneration	12	0
Retinal detachment	30	0
Retinal drusen	1	0
Retinal tear	19	0
Retinal toxicity	5	0
Vitreoretinal traction syndrome	1	0
<b><i>Retinal, choroid and vitreous infections and inflammations</i></b>		
Cystoid macular oedema	1	0
Macular oedema	8	0
Retinal oedema	2	0
Retinal vasculitis	1	0
<b><i>Retinopathies NEC</i></b>		
Acute macular neuroretinopathy	5	0
Diabetic retinopathy	3	0
Retinal exudates	18	0
Retinopathy	8	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	21	0
Scleritis	14	0
<b><i>Scleral structural change, deposit and degeneration</i></b>		
Scleral discolouration	1	0
<b><i>Structural change, deposit and degeneration of eye NEC</i></b>		
Deposit eye	1	0
Endocrine ophthalmopathy	5	0
Exophthalmos	6	0
Eye opacity	1	0
<b><i>Visual colour distortions</i></b>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	3	0
Erythropsia	7	0
Xanthopsia	9	0
<b><i>Visual disorders NEC</i></b>		
Charles Bonnet syndrome	1	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Delayed dark adaptation	1	0
Diplopia	358	0
Dysmetropsia	1	0
Halo vision	13	0
Metamorphopsia	42	0
Oscillopsia	1	0
Photopsia	343	0
Scintillating scotoma	10	0
Vision blurred	3101	0
Visual brightness	10	0
Visual snow syndrome	6	0
<b>Visual field disorders</b>		
Visual field defect	45	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Amaurosis	1	0
Amaurosis fugax	10	0
Blindness	312	0
Blindness day	1	0
Blindness transient	27	0
Blindness unilateral	44	0
Central vision loss	3	0
Night blindness	6	0
Sudden visual loss	6	0
Visual acuity reduced	40	0
Visual acuity reduced transiently	1	0
Visual impairment	821	0
<b>Visual pathway disorders</b>		
Optic nerve compression	2	0
Optic nerve disorder	5	0
Optic neuropathy	10	0
<b>Eye disorders SOC TOTAL</b>	<b>14685</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	4	0
Gastrointestinal sounds abnormal	26	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
Internal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	42	2
Pancreatitis acute	21	0
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
<i>Anal and rectal pains</i>		
Proctalgia	28	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	2	0
Anal hypoaesthesia	7	0
Anal inflammation	2	0
Anal paraesthesia	2	0
Anal pruritus	7	0
Anal spasm	1	0
Anorectal discomfort	12	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal spasm	2	0
Rectal tenesmus	2	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	2	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	14	0
Tongue cyst	5	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	4	0
Colitis	63	0
Colitis ischaemic	8	1
Colitis microscopic	6	0
Colitis ulcerative	113	0
Crohn's disease	108	0
Inflammatory bowel disease	15	0
Terminal ileitis	1	0
<i>Cystic pancreatic disorders</i>		
Pancreatic cyst	1	0
Pancreatic pseudocyst	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	7	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		
Tooth impacted	1	0
<i>Dental disorders NEC</i>		
Diastema	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Loose tooth	3	0
Malpositioned teeth	3	0
Teething	22	0
Tooth disorder	5	0
Tooth socket haemorrhage	2	0
<b><i>Dental pain and sensation disorders</i></b>		
Dental discomfort	12	0
Dental paraesthesia	18	0
Hyperaesthesia teeth	67	0
Hypoaesthesia teeth	2	0
Toothache	345	0
<b><i>Dental pulp disorders</i></b>		
Dental pulp disorder	1	0
<b><i>Dental surface disorders</i></b>		
Tooth discolouration	19	0
<b><i>Diaphragmatic hernias</i></b>		
Hiatus hernia	21	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	8993	0
Diarrhoea haemorrhagic	34	0
<b><i>Diverticula</i></b>		
Diverticulum	11	0
Diverticulum intestinal	1	0
<b><i>Duodenal and small intestinal stenosis and obstruction</i></b>		
Small intestinal obstruction	1	0
Superior mesenteric artery syndrome	1	0
<b><i>Duodenal ulcers and perforation</i></b>		
Duodenal ulcer	2	0
Duodenal ulcer haemorrhage	2	1
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	907	0
Epigastric discomfort	20	0
Eructation	110	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	27	0
Faecaloma	4	0
Faeces discoloured	56	0
Faeces hard	4	0
Faeces pale	7	0
Faeces soft	23	0
Mucous stools	16	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	727	0
Flatulence	404	0
<b><i>Gastric and oesophageal haemorrhages</i></b>		
Gastric haemorrhage	16	1
<b><i>Gastric ulcers and perforation</i></b>		
Gastric ulcer	13	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
<b><i>Gastritis (excl infective)</i></b>		
Chronic gastritis	5	0
Gastritis	114	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Reflux gastritis	17	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	3	0
Abdominal pain	4610	0
Abdominal pain lower	269	0
Abdominal pain upper	5332	0
Abdominal rigidity	64	0
Abdominal tenderness	23	0
Gastrointestinal pain	327	0
Oesophageal pain	9	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	501	0
Duodenogastric reflux	4	0
Gastric dilatation	18	0
Gastrooesophageal reflux disease	245	0
Impaired gastric emptying	7	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Oesophageal hypomotility	1	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Appendix disorder	3	0
Food poisoning	13	0
Functional gastrointestinal disorder	21	0
Gastric disorder	15	0
Gastrointestinal disorder	50	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	3	0
Stomach mass	2	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	8	0
Change of bowel habit	22	0
Dyschezia	13	0
Gastrointestinal motility disorder	5	0
Oesophageal achalasia	5	0
<b><i>Gastrointestinal fistulae</i></b>		
Anal fistula	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Appendicitis noninfective	2	0
Duodenitis	1	0
Enteritis	1	0
Gastrointestinal inflammation	2	0
Gastrointestinal tract irritation	4	0
Intestinal angioedema	1	0
Ischaemic enteritis	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Achlorhydria	1	0
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<b><i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i></b>		
Gastrointestinal necrosis	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	1610	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal symptom	6	0
Acute abdomen	18	0
Anal incontinence	56	0
Breath odour	25	0
Dysphagia	297	0
Intestinal congestion	1	0
Odynophagia	34	0
Oesophageal discomfort	1	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Cardiospasm	2	1
Defaecation urgency	17	0
Frequent bowel movements	50	0
Irritable bowel syndrome	160	0
Oesophageal spasm	9	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	7	0
Intussusception	1	0
Volvulus	1	1
<b><i>Gastrointestinal ulcers and perforation, site unspecified</i></b>		
Diverticular perforation	2	0
Gastrointestinal perforation	1	0
Gastrointestinal ulcer	1	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	12	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal infarction	6	1
Intestinal ischaemia	36	1
Mesenteric artery embolism	1	0
Mesenteric artery stenosis	1	0
Mesenteric artery thrombosis	5	0
Mesenteric vein thrombosis	23	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	4	0
Visceral venous thrombosis	15	1
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Amalgam tattoo	1	0
Epulis	1	0
Gingival atrophy	1	0
Gingival blister	23	0
Gingival discolouration	1	0
Gingival discomfort	7	0
Gingival disorder	17	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	238	0
Gingival pruritus	1	0
Gingival recession	3	0
Gingival swelling	57	0
Gingival ulceration	10	0
Gingivitis ulcerative	2	0
Noninfective gingivitis	24	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	182	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Anorectal varices	1	0
Haemorrhoidal haemorrhage	4	0
Haemorrhoids	69	0
Haemorrhoids thrombosed	15	0
<b><i>Inguinal hernias</i></b>		
Inguinal hernia	4	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	52	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	5	0
Rectal haemorrhage	120	0
Small intestinal haemorrhage	27	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	5	0
Large intestine perforation	1	0
<b><i>Large intestinal stenosis and obstruction</i></b>		
Large intestinal obstruction	1	0
Large intestinal stenosis	1	0
<b><i>Malabsorption syndromes</i></b>		
Bile acid malabsorption	1	0
Coeliac disease	24	0
Steatorrhoea	2	0
<b><i>Nausea and vomiting symptoms</i></b>		
Acetonaemic vomiting	1	0
Cyclic vomiting syndrome	2	0
Discoloured vomit	19	0
Faecal vomiting	3	0
Infantile spitting up	1	0
Infantile vomiting	6	0
Nausea	33566	0
Regurgitation	3	0
Retching	237	0
Vomiting	11448	0
Vomiting projectile	156	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	40	1
Haematemesis	81	0
Haematochezia	105	0
Intra-abdominal haematoma	2	0
Intra-abdominal haemorrhage	2	0
Melaena	10	0
Upper gastrointestinal haemorrhage	10	0
<b><i>Oesophageal disorders NEC</i></b>		
Oesophageal disorder	2	0
<b><i>Oesophageal stenosis and obstruction</i></b>		
Acquired oesophageal web	1	0
Oesophageal obstruction	1	0
<b><i>Oesophageal ulcers and perforation</i></b>		
Oesophageal rupture	1	1
Oesophageal ulcer	1	0
<b><i>Oesophageal varices</i></b>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Varices oesophageal	3	0
<b><i>Oesophagitis (excl infective)</i></b>		
Eosinophilic oesophagitis	3	0
Oesophagitis	21	0
<b><i>Oral dryness and saliva altered</i></b>		
Aptyalism	5	0
Dry mouth	1161	0
Lip dry	79	0
Saliva altered	8	0
Saliva discolouration	1	0
Salivary hypersecretion	94	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Angina bullosa haemorrhagica	4	0
Chapped lips	25	0
Cheilitis	40	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	37	0
Lip disorder	6	0
Oral disorder	20	0
Oral lichen planus	16	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Lip haemorrhage	4	0
Mouth haemorrhage	59	0
Oral blood blister	55	0
Oral purpura	2	0
<b><i>Oral soft tissue infections</i></b>		
Angular cheilitis	11	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Anaesthesia oral	8	0
Burning mouth syndrome	16	0
Coating in mouth	4	0
Hypoaesthesia oral	675	0
Lip discolouration	2	0
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	61	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	109	0
Oral dysaesthesia	1	0
Oral mucosal blistering	34	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	31	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral pain	369	0
Oral pruritus	21	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Paraesthesia oral	862	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip oedema	10	0
Lip swelling	1000	0
Mouth swelling	137	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	14	0
<b><i>Pancreatic disorders NEC</i></b>		
Pancreatic disorder	1	0
Pancreatic failure	2	0
Pancreatic mass	1	0
Pancreatic steatosis	1	0
<b><i>Peptic ulcers and perforation</i></b>		
Peptic ulcer	2	0
Peptic ulcer haemorrhage	9	0
<b><i>Peritoneal and retroperitoneal disorders</i></b>		
Ascites	9	0
Pneumoperitoneum	1	0
<b><i>Peritoneal and retroperitoneal fibrosis and adhesions</i></b>		
Abdominal adhesions	2	0
<b><i>Peritoneal and retroperitoneal haemorrhages</i></b>		
Haemoperitoneum	2	0
Retroperitoneal haemorrhage	1	0
<b><i>Rectal inflammations NEC</i></b>		
Proctitis	5	0
<b><i>Salivary gland disorders NEC</i></b>		
Salivary gland calculus	4	0
Salivary gland cyst	1	0
Salivary gland mass	2	0
Salivary gland pain	13	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	14	0
Salivary gland enlargement	6	0
<b><i>Salivary gland infections and inflammations</i></b>		
Noninfective sialoadenitis	2	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	66	0
Lip ulceration	18	0
Mouth ulceration	772	0
Stomatitis	108	0
<b><i>Tongue disorders</i></b>		
Acquired macroglossia	1	0
Glossitis	18	0
Plicated tongue	4	0
Tongue disorder	35	0
Tongue geographic	5	0
Tongue haemorrhage	2	0
Tongue ulceration	32	0
Trichoglossia	7	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	265	0
Scalloped tongue	4	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Stiff tongue	6	0
Strawberry tongue	1	0
Swollen tongue	633	0
Tongue blistering	28	0
Tongue coated	36	0
Tongue discolouration	40	0
Tongue discomfort	58	0
Tongue dry	23	0
Tongue eruption	12	0
Tongue erythema	7	0
Tongue exfoliation	2	0
Tongue movement disturbance	9	0
Tongue oedema	17	0
Tongue pruritus	3	0
Tongue rough	3	0
Tongue spasm	5	0
<i>Tooth missing</i>		
Tooth loss	10	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>80554</b>	<b>13</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	18	0
Administration site coldness	1	0
Administration site erythema	6	0
Administration site extravasation	1	0
Administration site haemorrhage	1	0
Administration site indentation	1	0
Administration site induration	1	0
Administration site injury	1	0
Administration site irritation	1	0
Administration site mass	1	0
Administration site movement impairment	1	0
Administration site pain	45	0
Administration site rash	5	0
Administration site reaction	6	0
Administration site swelling	3	0
Administration site urticaria	5	0
Administration site warmth	2	0
Puncture site bruise	61	0
Puncture site haemorrhage	1	0
Puncture site pain	22	0
Puncture site reaction	3	0
Puncture site swelling	1	0
Vessel puncture site bruise	2	0
<b><i>Adverse effect absent</i></b>		
No adverse event	4	0
<b><i>Application and instillation site reactions</i></b>		
Application site acne	1	0
Application site bruise	25	0
Application site burn	4	0
Application site coldness	2	0
Application site discharge	1	0
Application site discolouration	2	0
Application site erythema	29	0
Application site exfoliation	1	0
Application site haemorrhage	1	0
Application site hypersensitivity	1	0
Application site hypoaesthesia	2	0
Application site inflammation	2	0
Application site joint pain	1	0
Application site laceration	1	0
Application site movement impairment	1	0
Application site odour	1	0
Application site pain	52	0
Application site pruritus	20	0
Application site rash	4	0
Application site reaction	1	0
Application site scar	1	0
Application site swelling	4	0
Application site vesicles	14	0
Application site warmth	2	0
Application site wound	1	0
Instillation site bruise	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Instillation site discomfort	1	0
Instillation site pain	5	0
Instillation site pruritus	1	0
Instillation site warmth	12	0
<b><i>Asthenic conditions</i></b>		
Asthenia	5125	2
Chronic fatigue syndrome	168	0
Decreased activity	16	0
Fatigue	50945	0
Malaise	12755	0
Sluggishness	30	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	13	0
Hypothermia	58	0
Temperature regulation disorder	29	0
<b><i>Breast complications associated with device</i></b>		
Capsular contracture associated with breast implant	1	0
<b><i>Complications associated with device NEC</i></b>		
Complication of device removal	1	0
Injury associated with device	10	0
Medical device site dysaesthesia	1	0
Medical device site joint pain	1	0
Phantom shocks	4	0
<b><i>Death and sudden death</i></b>		
Brain death	4	3
Cardiac death	7	7
Death	326	326
Drowning	1	0
Hanging	1	1
Sudden cardiac death	1	1
Sudden death	41	41
Sudden unexplained death in epilepsy	1	1
<b><i>Febrile disorders</i></b>		
Hyperpyrexia	42	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	55511	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	43202	0
Early satiety	1	0
Feeling abnormal	3396	0
Feeling cold	5289	0
Feeling drunk	133	0
Feeling hot	2479	0
Feeling jittery	47	0
Feeling of body temperature change	971	0
Feeling of relaxation	2	0
Hangover	197	0
Humidity intolerance	1	0
Hunger	83	0
Sensation of blood flow	17	0
Sensation of foreign body	55	0
Temperature intolerance	90	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Thirst	1273	0
Thirst decreased	11	0
<b>Fibrosis NEC</b>		
Fibrosis	7	0
<b>Gait disturbances</b>		
Decreased gait velocity	3	0
Gait disturbance	499	0
Gait inability	234	0
Loss of control of legs	62	0
<b>General signs and symptoms NEC</b>		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	338	0
Crepitations	10	0
Crying	303	0
Deformity	1	0
Developmental delay	3	0
Discharge	10	0
Disease prodromal stage	1	0
Disease progression	3	1
Disease recurrence	2	0
Effusion	2	0
Energy increased	26	0
Exercise tolerance decreased	45	0
Foaming at mouth	6	0
General physical health deterioration	31	2
General symptom	11	0
Glassy eyes	8	0
High-pitched crying	8	0
Ill-defined disorder	12	0
Illness	5137	1
Impaired self-care	1	0
Induration	22	0
Influenza like illness	9690	0
Irritability postvaccinal	3	0
Local reaction	155	0
Moaning	9	0
Multiple organ dysfunction syndrome	25	13
Nonspecific reaction	3	0
Organ failure	3	0
Perforation	2	0
Performance status decreased	1	0
Peripheral swelling	6019	0
Pre-existing condition improved	19	0
Premature ageing	3	0
Prolapse	1	0
Screaming	32	0
Secretion discharge	36	0
Sensitivity to weather change	3	0
Stenosis	2	0
Swelling	2835	0
Swelling face	1110	0
Symptom masked	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Symptom recurrence	4	0
Tissue discolouration	1	0
Tissue infiltration	1	0
Unevaluable event	9	0
<b>Healing abnormal NEC</b>		
Impaired healing	7	0
<b>Hernias NEC</b>		
Hernia	6	0
<b>Implant and catheter site reactions</b>		
Catheter site urticaria	1	0
Implant site coldness	1	0
Implant site discharge	1	0
Implant site discolouration	4	0
Implant site hypoaesthesia	2	0
Implant site pain	4	0
Implant site rash	1	0
Implant site swelling	3	0
Implant site urticaria	3	0
Implant site vesicles	1	0
Implant site warmth	7	0
<b>Inflamations</b>		
Granuloma	2	0
Inflammation	882	0
Papillitis	1	0
Scar inflammation	1	0
Systemic inflammatory response syndrome	8	0
<b>Infusion site reactions</b>		
Infusion site bruising	1	0
Infusion site discomfort	1	0
Infusion site erythema	3	0
Infusion site joint pain	1	0
Infusion site mass	5	0
Infusion site mobility decreased	1	0
Infusion site nodule	2	0
Infusion site pain	14	0
Infusion site urticaria	2	0
Infusion site warmth	6	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	46	0
Injection site atrophy	9	0
Injection site bruising	126	0
Injection site coldness	6	0
Injection site cyst	6	0
Injection site deformation	1	0
Injection site discharge	1	0
Injection site discolouration	8	0
Injection site discomfort	21	0
Injection site dryness	1	0
Injection site erythema	597	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	3	0
Injection site haemorrhage	20	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site hypersensitivity	5	0
Injection site hypoaesthesia	16	0
Injection site indentation	22	0
Injection site induration	10	0
Injection site inflammation	67	0
Injection site injury	4	0
Injection site irritation	4	0
Injection site joint discomfort	1	0
Injection site joint erythema	8	0
Injection site joint pain	35	0
Injection site joint swelling	1	0
Injection site mass	1429	0
Injection site movement impairment	5	0
Injection site muscle weakness	2	0
Injection site necrosis	7	0
Injection site nerve damage	2	0
Injection site nodule	4	0
Injection site oedema	28	0
Injection site pain	4531	0
Injection site papule	2	0
Injection site paraesthesia	26	0
Injection site pruritus	301	0
Injection site rash	310	0
Injection site reaction	123	0
Injection site scab	4	0
Injection site scar	6	0
Injection site swelling	264	0
Injection site thrombosis	1	0
Injection site ulcer	1	0
Injection site urticaria	41	0
Injection site vesicles	16	0
Injection site warmth	356	0
<b>Interactions</b>		
Drug interaction	35	0
Food interaction	2	0
Inhibitory drug interaction	12	0
<b>Mass conditions NEC</b>		
Cyst	38	0
Mass	93	0
Nodule	26	0
Pelvic mass	1	0
<b>Mucosal findings abnormal</b>		
Mucosa vesicle	2	0
Mucosal disorder	2	0
Mucosal dryness	1	0
Mucosal haemorrhage	12	0
Mucosal inflammation	11	0
Mucosal pain	2	0
Mucosal ulceration	1	0
Oedema mucosal	3	0
Polyp	5	0
<b>Necrosis NEC</b>		
Fat necrosis	4	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Necrosis	8	0
<b>Oedema NEC</b>		
Face oedema	36	0
Localised oedema	13	0
Oedema	94	0
Oedema peripheral	167	0
<b>Pain and discomfort NEC</b>		
Axillary pain	776	0
Chest discomfort	2151	0
Chest pain	5977	0
Discomfort	654	0
Facial discomfort	22	0
Facial pain	298	0
Hernia pain	4	0
Inflammatory pain	37	0
Non-cardiac chest pain	47	0
Pain	17796	0
Suprapubic pain	1	0
Tenderness	1849	0
Visceral pain	2	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	46	0
Adverse event	9	0
Adverse food reaction	1	0
Adverse reaction	12	0
Diet failure	1	0
Drug effect less than expected	1	0
Drug ineffective	181	1
Drug intolerance	9	0
Idiosyncratic drug reaction	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	32	0
No reaction on previous exposure to drug	10	0
Remission not achieved	1	0
Similar reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	4	0
Therapeutic product effect delayed	1	0
Therapeutic product effect incomplete	2	0
Therapeutic product effect prolonged	1	0
Therapeutic product ineffective	9	0
Therapeutic reaction time decreased	1	0
Therapeutic response changed	1	0
Therapeutic response decreased	1	0
Therapeutic response delayed	1	0
Therapeutic response shortened	2	0
Therapeutic response unexpected	181	0
Therapy non-responder	3	0
Treatment failure	20	0
Treatment noncompliance	1	0
Vaccination failure	42	0
Vaccine positive rechallenge	1	0
<b>Trophic disorders</b>		
Atrophy	4	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Calcinosis	2	0
Dysplasia	3	0
Hyperplasia	2	0
<b>Ulcers NEC</b>		
Ulcer	48	0
Ulcer haemorrhage	3	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	19	0
Shoulder injury related to vaccine administration	102	0
Vaccination site atrophy	1	0
Vaccination site bruising	139	0
Vaccination site coldness	1	0
Vaccination site cyst	3	0
Vaccination site discharge	1	0
Vaccination site discolouration	18	0
Vaccination site discomfort	50	0
Vaccination site dryness	1	0
Vaccination site erythema	720	0
Vaccination site extravasation	1	0
Vaccination site granuloma	8	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	10	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	25	0
Vaccination site induration	70	0
Vaccination site inflammation	56	0
Vaccination site injury	4	0
Vaccination site irritation	15	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	5	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	18	0
Vaccination site joint pain	54	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	2	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	568	0
Vaccination site movement impairment	106	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	2131	0
Vaccination site papule	4	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	112	0
Vaccination site rash	195	0
Vaccination site reaction	26	0
Vaccination site scab	2	0
Vaccination site scar	7	0
Vaccination site swelling	517	0
Vaccination site urticaria	12	0
Vaccination site vesicles	11	0
Vaccination site warmth	382	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<i>Vascular complications associated with device</i>		
Vascular stent occlusion	1	0
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	104	0
<b>General disorders SOC TOTAL</b>	<b>255297</b>	<b>400</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	33	0
Cholangitis	3	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	16	0
Cholecystitis acute	3	0
Cholelithiasis	16	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	7	0
Jaundice	57	0
Jaundice cholestatic	12	0
Ocular icterus	1	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	4	0
Gallbladder oedema	1	0
Gallbladder polyp	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	21	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	13	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	2	0
Hepatic failure	12	1
Hepatorenal syndrome	1	0
Subacute hepatic failure	3	0
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	10	1
<i><b>Hepatic vascular disorders</b></i>		
Budd-Chiari syndrome	2	1
Hepatic artery thrombosis	1	0
Hepatic haemorrhage	1	0
Hepatic hypoperfusion	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	0
Hepatic vein thrombosis	16	0
Portal hypertension	4	0
Portal vein phlebitis	1	0
Portal vein thrombosis	73	4
Portosplenomesenteric venous thrombosis	2	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	80	0
Hepatomegaly	5	0
Liver tenderness	6	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Acute yellow liver atrophy	1	0
Allergic hepatitis	1	0
Autoimmune hepatitis	11	0
Cholestatic liver injury	1	0
Drug-induced liver injury	2	0
Hepatic necrosis	1	0
Hepatic steatosis	12	0
Hepatitis	32	0
Hepatitis acute	8	1

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b> Hepatic disorders cont'd		
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0
Liver injury	30	0
Nonalcoholic fatty liver disease	1	0
Reye's syndrome	1	0
<b><i>Obstructive bile duct disorders (excl neoplasms)</i></b>		
Biliary obstruction	1	0
Sphincter of Oddi dysfunction	3	0
<b>Hepatic disorders SOC TOTAL</b>	<b>519</b>	<b>9</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	29	0
<i>Allergic conditions NEC</i>		
Allergic oedema	22	0
Allergy to animal	1	0
Allergy to arthropod bite	1	0
Allergy to arthropod sting	5	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	3	0
Hypersensitivity	1557	1
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	23	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	7	0
Type IV hypersensitivity reaction	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	3	0
Allergy to chemicals	9	0
Allergy to vaccine	61	0
Contrast media reaction	4	0
Drug hypersensitivity	71	0
Food allergy	55	0
Milk allergy	1	0
Oral allergy syndrome	5	0
Polymers allergy	1	0
Reaction to colouring	2	0
Reaction to excipient	14	0
Reaction to preservatives	15	0
Rubber sensitivity	3	0
Smoke sensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	716	2
Anaphylactic shock	125	0
Anaphylactoid reaction	23	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	5	0
Seasonal allergy	149	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	70	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Endocrine autoimmune disorders</i>		
Hashitoxicosis	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	36	0
Cytokine release syndrome	2	0
Cytokine storm	6	0

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
Immune system disorders cont'd		
Decreased immune responsiveness	1	0
Haemophagocytic lymphohistiocytosis	14	1
Hypocomplementaemia	1	0
Immune system disorder	56	0
Immune-mediated adverse reaction	10	0
Immunisation reaction	1	0
Multiple chemical sensitivity	2	0
Pre-engraftment immune reaction	1	0
Sensitisation	34	0
<b>Immunodeficiency disorders NEC</b>		
Immunodeficiency	14	0
Immunosuppression	7	0
<b>Transplant rejections</b>		
Corneal graft rejection	3	0
Transplant rejection	7	0
<b>Vasculitides</b>		
Anti-neutrophil cytoplasmic antibody positive vasculitis	4	1
Eosinophilic granulomatosis with polyangiitis	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>3233</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Abdominal infection	1	0
Abdominal wall infection	1	0
Anal abscess	1	0
Appendicitis	43	0
Appendicitis perforated	4	0
Diarrhoea infectious	4	0
Diverticulitis	34	0
Dysentery	5	0
Gastric infection	1	0
Gastroenteritis	46	0
Gastrointestinal infection	5	0
Large intestine infection	2	0
Peritonitis	3	0
<b><i>Adenoviral infections</i></b>		
Adenovirus infection	1	0
<b><i>Bacillary infections</i></b>		
Bacillus infection	1	0
Gastroenteritis bacillus	1	0
<b><i>Bacterial infections NEC</i></b>		
Abscess bacterial	1	0
Administration site cellulitis	1	0
Arthritis bacterial	10	0
Bacterial infection	34	1
Bacterial vaginosis	4	0
Bacterial vulvovaginitis	1	0
Cellulitis	541	0
Cellulitis orbital	2	0
Ear infection bacterial	2	0
Endocarditis bacterial	2	0
Eye infection bacterial	1	0
Folliculitis	12	0
Gangrene	3	0
Injection site cellulitis	8	0
Meningitis bacterial	1	0
Perichondritis	1	0
Periorbital cellulitis	5	0
Pneumonia bacterial	6	1
Post procedural cellulitis	1	0
Skin bacterial infection	6	0
Urinary tract infection bacterial	5	0
Vaccination site cellulitis	22	0
<b><i>Bone and joint infections</i></b>		
Abscess jaw	1	0
Arthritis infective	4	0
Bursitis infective	3	0
Intervertebral discitis	3	0
Osteomyelitis	2	1
<b><i>Bordetella infections</i></b>		
Pertussis	3	0
<b><i>Borreliac infections</i></b>		
Erythema migrans	2	0
Lyme disease	8	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Relapsing fever	1	0
<b>Breast infections</b>		
Breast abscess	2	0
Mastitis	47	0
<b>Brucella infections</b>		
Brucellosis	1	0
<b>Caliciviral infections</b>		
Gastroenteritis norovirus	1	0
Norovirus infection	1	0
<b>Campylobacter infections</b>		
Campylobacter colitis	1	0
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<b>Candida infections</b>		
Anal candidiasis	2	0
Balanitis candida	1	0
Candida infection	82	0
Oral candidiasis	62	0
Skin candida	3	0
Vulvovaginal candidiasis	59	0
<b>Cardiac infections</b>		
Acute endocarditis	2	0
Cardiac infection	1	0
Endocarditis	8	0
Myocarditis infectious	1	0
<b>Central nervous system and spinal infections</b>		
Brain abscess	3	0
Cavernous sinus thrombosis	9	0
Central nervous system infection	2	0
Encephalitis	47	0
Encephalomyelitis	3	0
Extradural abscess	1	0
Meningitis	30	0
Myelitis	26	0
<b>Chlamydial infections</b>		
Chlamydial infection	1	0
<b>Clostridia infections</b>		
Clostridium difficile colitis	5	0
Clostridium difficile infection	3	0
Tetanus	4	0
<b>Coronavirus infections</b>		
Asymptomatic COVID-19	5	0
COVID-19	1473	29
COVID-19 pneumonia	73	10
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	19	0
SARS-CoV-2 sepsis	1	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	48	0
Vaccine derived SARS-CoV-2 infection	1	0
<b>Corynebacteria infections</b>		
Diphtheria	3	0
<b>Coxiella infections</b>		

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Q fever	113	0
<b>Coxsackie viral infections</b>		
Coxsackie bronchitis	1	0
<b>Cytomegaloviral infections</b>		
Encephalitis cytomegalovirus	1	0
<b>Dental and oral soft tissue infections</b>		
Abscess oral	4	0
Gingival abscess	9	0
Gingivitis	31	0
Lip infection	1	0
Oral infection	1	0
Oral pustule	3	0
Parotitis	15	0
Pericoronitis	3	0
Periodontitis	2	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	5	0
Tooth abscess	16	0
Tooth infection	15	0
<b>Ear infections</b>		
Ear infection	148	0
Labyrinthitis	192	0
Mastoiditis	5	0
Otitis externa	7	0
Otitis media	9	0
Otitis media chronic	14	0
Otosalpingitis	1	0
<b>Ectoparasitic infestations</b>		
Acarodermatitis	10	0
Infestation	1	0
Trombidiasis	3	0
<b>Epstein-Barr viral infections</b>		
Epstein-Barr virus infection	6	0
Epstein-Barr virus infection reactivation	2	0
Infectious mononucleosis	59	0
<b>Escherichia infections</b>		
Escherichia infection	2	0
Escherichia sepsis	2	0
Gastroenteritis Escherichia coli	1	0
<b>Eye and eyelid infections</b>		
Conjunctivitis	87	0
Eye infection	47	0
Eyelid boil	3	0
Eyelid infection	4	0
Hordeolum	42	0
Keratouveitis	1	0
Retinitis	3	0
<b>Female reproductive tract infections</b>		
Endometritis	3	0
Fallopian tube abscess	1	0
Genital infection female	1	0
Ovarian abscess	1	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Pelvic inflammatory disease	2	0
Pyometra	2	1
Vaginal abscess	3	0
Vaginal infection	6	0
Vulval abscess	1	0
<b>Flaviviral infections</b>		
Dengue fever	1	0
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1	0
<b>Fungal infections NEC</b>		
Ear infection fungal	2	0
Fungal infection	31	0
Fungal skin infection	10	0
Oral fungal infection	1	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
Severe asthma with fungal sensitisation	5	0
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	4	0
<b>Helicobacter infections</b>		
Helicobacter infection	1	0
<b>Hepatitis virus infections</b>		
Hepatitis E	1	0
<b>Hepatobiliary and spleen infections</b>		
Biliary sepsis	5	1
Liver abscess	1	0
Splenic infection	1	0
<b>Herpes viral infections</b>		
Eczema herpeticum	3	0
Genital herpes	82	0
Genital herpes simplex	1	0
Genital herpes zoster	1	0
Haemorrhagic varicella syndrome	1	0
Herpes dermatitis	2	0
Herpes ophthalmic	16	0
Herpes pharyngitis	1	0
Herpes simplex	49	0
Herpes simplex reactivation	4	0
Herpes virus infection	16	0
Herpes zoster	1658	0
Herpes zoster disseminated	1	0
Herpes zoster oticus	15	0
Herpes zoster reactivation	2	0
Meningoencephalitis herpetic	2	0
Nasal herpes	16	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	10	0
Oral herpes	720	0
Varicella	42	0
Varicella zoster virus infection	4	0
<b>Infections NEC</b>		
Abscess	53	0
Abscess limb	25	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Abscess soft tissue	2	0
Catheter site infection	1	0
Coinfection	1	0
Device related infection	3	0
Empyema	1	0
Genital abscess	1	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	5	0
Infected cyst	4	0
Infection	545	4
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	21	0
Localised infection	108	0
Lymph gland infection	9	0
Lymph node abscess	2	0
Omphalitis	1	0
Pathogen resistance	3	0
Pelvic infection	1	0
Purulence	1	0
Pyuria	1	0
Respiratory tract infection	9	0
Toxic shock syndrome	1	0
Vaccination site abscess	7	0
Vaccination site infection	24	0
Vaccine breakthrough infection	3	0
Vestibulitis	4	0
Wound abscess	1	0
<b><i>Infectious disorders carrier</i></b>		
SARS-CoV-2 carrier	1	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	16	0
Vaccine virus shedding	1	0
<b><i>Influenza viral infections</i></b>		
H1N1 influenza	1	0
H2N2 influenza	3	0
Influenza	6830	0
<b><i>Klebsiella infections</i></b>		
Cystitis klebsiella	1	0
Pneumonia klebsiella	1	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Atypical pneumonia	2	0
Bronchitis	28	0
Infectious pleural effusion	4	0
Infective exacerbation of bronchiectasis	1	0
Infective pulmonary exacerbation of cystic fibrosis	1	1
Lower respiratory tract infection	332	4
Pleural infection	1	0
Pneumonia	279	30
Pneumonia aspiration	26	5
Sputum purulent	3	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	9	0
Orchitis	6	0
<b><i>Molluscum contagiosum viral infections</i></b>		
Molluscum contagiosum	1	0
<b><i>Mumps viral infections</i></b>		
Mumps	13	0
<b><i>Muscle and soft tissue infections</i></b>		
Muscle abscess	1	0
Necrotising fasciitis	1	0
Soft tissue infection	5	0
<b><i>Neisseria infections</i></b>		
Gonorrhoea	1	0
<b><i>Orthopox viral infections</i></b>		
Cow pox	1	0
Vaccinia virus infection	2	0
<b><i>Papilloma viral infections</i></b>		
Papilloma viral infection	1	0
<b><i>Paravaccinia infections</i></b>		
Paravaccinia	1	0
<b><i>Phleboviral infections</i></b>		
Severe fever with thrombocytopenia syndrome	2	0
<b><i>Plasmodia infections</i></b>		
Malaria	7	0
<b><i>Pneumocystis infections</i></b>		
Pneumocystis jirovecii pneumonia	1	0
<b><i>Prion-associated disorders</i></b>		
Creutzfeldt-Jakob disease	3	0
<b><i>Pseudomonal infections</i></b>		
Pseudomonas infection	1	0
<b><i>Retroviral infections</i></b>		
Acquired immunodeficiency syndrome	2	0
HIV infection	3	0
HIV-associated neurocognitive disorder	1	0
Persistent generalised lymphadenopathy	1	0
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
Rotavirus infection	1	0
<b><i>Rubella viral infections</i></b>		
Rubella	1	0
<b><i>Rubeola viral infections</i></b>		
Measles	6	0
<b><i>Salmonella infections</i></b>		
Typhoid fever	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Abdominal sepsis	2	0
Bacteraemia	1	0
Neutropenic sepsis	9	0
Pelvic sepsis	1	0
Pulmonary sepsis	1	0
Sepsis	119	14
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Septic rash	13	0
Septic shock	5	1
Urosepsis	11	1
Viraemia	4	0
<b><i>Skin structures and soft tissue infections</i></b>		
Blister infected	1	0
Carbuncle	1	0
Dermatitis infected	10	0
Dermo-hypodermatitis	1	0
Eczema infected	3	0
Impetigo	13	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	27	0
Pyoderma	1	0
Rash pustular	19	0
Skin infection	75	0
Subcutaneous abscess	9	0
Vaccination site pustule	5	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	56	0
Pneumonia staphylococcal	1	0
Staphylococcal bacteraemia	2	0
Staphylococcal infection	3	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	4	1
Toxic shock syndrome staphylococcal	1	0
Vulvovaginitis staphylococcal	1	0
Wound infection staphylococcal	1	0
<b><i>Streptococcal infections</i></b>		
Beta haemolytic streptococcal infection	1	0
Cellulitis streptococcal	1	0
Erysipelas	1	0
Meningitis pneumococcal	2	1
Pharyngitis streptococcal	9	0
Pneumonia pneumococcal	1	0
Scarlet fever	1	0
Streptococcal bacteraemia	1	0
Streptococcal infection	3	0
Streptococcal sepsis	1	0
Tonsillitis streptococcal	1	0
<b><i>Tinea infections</i></b>		
Body tinea	9	0
Tinea cruris	3	0
Tinea infection	3	0
Tinea pedis	4	0
Tinea versicolour	2	0
<b><i>Treponema infections</i></b>		
Neurosyphilis	1	0
Pinta	1	0
Syphilis	4	0
<b><i>Trypanosomal infections</i></b>		
African trypanosomiasis	6	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
<b><i>Tuberculous infections</i></b>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Erythema induratum	1	0
Lymph node tuberculosis	3	0
Meningitis tuberculous	1	0
Pulmonary tuberculosis	2	0
Tuberculosis	4	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	6	0
Chronic sinusitis	17	0
Chronic tonsillitis	1	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	38	0
Nasal vestibulitis	1	0
Nasopharyngitis	1932	0
Peritonsillar abscess	1	0
Pharyngeal abscess	1	0
Pharyngitis	43	0
Rhinitis	57	0
Sinobronchitis	1	0
Sinusitis	402	0
Tonsillitis	89	0
Tracheitis	2	0
Upper respiratory tract infection	11	0
<b><i>Urinary tract infections</i></b>		
Cystitis	103	0
Genitourinary tract infection	1	0
Kidney infection	61	0
Pyelonephritis	7	0
Pyelonephritis acute	1	0
Pyelonephritis chronic	1	0
Renal abscess	2	0
Urethritis	1	0
Urinary tract infection	275	0
<b><i>Vascular infections</i></b>		
Haematoma infection	2	0
Infected lymphocele	1	0
Infected varicose vein	1	0
Lymphangitis	6	0
<b><i>Viral infections NEC</i></b>		
Arthritis viral	2	0
Bronchitis viral	1	0
Conjunctivitis viral	1	0
Ear infection viral	2	0
Encephalitis viral	8	0
Eye infection viral	1	0
Gastritis viral	1	0
Gastroenteritis viral	69	0
Gastrointestinal viral infection	1	0
Hepatitis viral	3	0
Meningitis viral	21	0
Pleurisy viral	1	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Pneumonia viral	12	1
Post viral fatigue syndrome	149	0
Sweating fever	740	0
Vestibular neuronitis	43	0
Viral diarrhoea	4	0
Viral infection	88	0
Viral labyrinthitis	7	0
Viral myelitis	1	0
Viral myocarditis	2	0
Viral pericarditis	5	0
Viral pharyngitis	31	0
Viral rash	81	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Viral upper respiratory tract infection	1	0
<b>Infections SOC TOTAL</b>	<b>19774</b>	<b>107</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Abdomen crushing	3	0
Abdominal injury	1	0
Colon injury	1	0
Lip injury	2	0
Mouth injury	3	0
Oral contusion	13	0
Palate injury	2	0
Pelvic bone injury	1	0
Splenic rupture	4	0
Tongue injury	3	0
Tooth fracture	2	0
Tooth injury	2	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	25	0
Accidental exposure to product packaging	1	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Airway complication of anaesthesia	2	0
Anaesthetic complication	3	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	6	0
Sedation complication	4	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotrauma	1	0
Decompression sickness	2	0
Hypobarism	3	0
<b><i>Bone and joint injuries NEC</i></b>		
Bursa injury	2	0
Cartilage injury	2	0
Joint injury	18	0
Synovial rupture	2	0
<b><i>Cardiac and vascular procedural complications</i></b>		
Deep vein thrombosis postoperative	1	0
Ischaemic contracture of the left ventricle	1	0
Vascular access site bruising	1	0
Vascular graft occlusion	1	0
Vascular graft thrombosis	1	0
Vascular pseudoaneurysm	1	0
Vasoplegia syndrome	1	0
<b><i>Cardiovascular injuries</i></b>		
Arterial injury	1	0
Vascular injury	13	0
Venous injury	1	0
<b><i>Cerebral injuries NEC</i></b>		
Brain contusion	16	0
Brain herniation	6	0
Concussion	10	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	2	0
Subarachnoid haematoma	3	0
Subdural haematoma	19	1
Subdural haemorrhage	6	0

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Traumatic intracranial haemorrhage	1	0
<b>Chemical injuries</b>		
Chemical burn	2	0
Chemical burn of oral cavity	2	0
Chemical burn of skin	7	0
Chemical phlebitis	2	0
<b>Chest and respiratory tract injuries NEC</b>		
Asbestosis	1	0
Chest crushing	16	0
Chest injury	2	0
Foreign body in throat	2	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
<b>Conditions caused by cold</b>		
Chillblains	76	0
Frostbite	1	0
<b>Cranial nerve injuries</b>		
Cranial nerve injury	1	0
Optic nerve injury	8	0
Vth nerve injury	1	0
<b>Ear injuries NEC</b>		
Deafness traumatic	1	0
<b>Exposures associated with pregnancy, delivery and lactation</b>		
Drug exposure before pregnancy	1	0
Exposure during pregnancy	21	0
Exposure via breast milk	113	0
Foetal exposure during pregnancy	34	0
Maternal exposure before pregnancy	15	0
Maternal exposure during breast feeding	1390	0
Maternal exposure during pregnancy	389	0
Maternal exposure timing unspecified	3	0
Paternal exposure during pregnancy	2	0
<b>Exposures to agents or circumstances NEC</b>		
Exposure to SARS-CoV-2	8	0
Exposure to household chemicals	1	0
Exposure to toxic agent	1	0
Exposure to vaccinated person	3	0
<b>Eye injuries NEC</b>		
Cataract traumatic	1	0
Eye contusion	58	0
Eye injury	54	0
Eyelid contusion	5	0
Foreign body in eye	2	0
Hyphaema	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Periorbital haemorrhage	1	0
Retinal injury	4	0
Superficial injury of eye	1	0
Traumatic iritis	1	0
<b>Foetal and neonatal conditions associated with product exposure</b>		
Intoxication by breast feeding	1	0
<b>Fractures and dislocations NEC</b>		

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Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Fracture	2	0
Joint dislocation	14	0
Multiple fractures	2	0
Stress fracture	4	0
Traumatic fracture	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Anastomotic ulcer	1	0
Peripancreatic fluid collection	1	0
Procedural nausea	27	0
Procedural vomiting	7	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat cramps	2	0
Heat exhaustion	4	0
Heat illness	4	0
Heat oedema	13	0
Heat stroke	11	0
<b><i>Intentional product misuses</i></b>		
Intentional product misuse	14	0
<b><i>Intentional product use issues</i></b>		
Intentional dose omission	20	0
Intentional product use issue	2	0
<b><i>Limb fractures and dislocations</i></b>		
Ankle fracture	3	0
Atypical femur fracture	1	0
Clavicle fracture	22	0
Femoral neck fracture	2	0
Femur fracture	2	0
Foot fracture	3	0
Humerus fracture	1	0
Lower limb fracture	3	0
Patella fracture	1	0
Tibia fracture	1	0
Upper limb fracture	3	0
Wrist fracture	3	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Circumstance or information capable of leading to medication error	15	0
Device use issue	1	0
Dose calculation error	3	0
Drug titration error	1	0
Inadequate aseptic technique in use of product	2	0
Intercepted medication error	6	0
Medication error	101	0
Prescription drug used without a prescription	2	0
Product use in unapproved indication	1	0
Product use issue	8	0
Vaccination error	11	0
Wrong device used	1	0
Wrong drug	5	0
Wrong route	1	0
Wrong schedule	2	0
Wrong technique in product usage process	10	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	30	0

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Ligament injury	3	0
Ligament rupture	2	0
Ligament sprain	23	0
Muscle injury	66	0
Muscle rupture	19	0
Muscle strain	56	0
Post-traumatic neck syndrome	4	0
Repetitive strain injury	3	0
Tendon injury	7	0
Tendon rupture	29	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	203	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Post lumbar puncture syndrome	8	0
Posterior fossa syndrome	1	0
Procedural dizziness	37	0
<b><i>Non-occupational environmental exposures</i></b>		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	2	0
<b><i>Non-site specific injuries NEC</i></b>		
Animal bite	1	0
Arthropod bite	8	0
Arthropod sting	13	0
Bite	1	0
Child maltreatment syndrome	1	0
Electric shock	35	0
Extraskeletal ossification	1	0
Fall	297	0
Foreign body	2	0
Inflammation of wound	4	0
Injury	21	0
Internal injury	1	0
Nervous system injury	4	0
Post concussion syndrome	2	0
Road traffic accident	2	0
Soft tissue injury	6	0
Sports injury	1	0
Struck by lightning	1	0
Tissue injury	4	0
Traumatic haematoma	3	0
Traumatic shock	1	0
Wound	10	0
Wound complication	15	0
Wound haemorrhage	11	0
Wound secretion	4	0
<b><i>Non-site specific procedural complications</i></b>		
Administration related reaction	2	0
Incision site erythema	1	0
Incision site haemorrhage	1	0
Incision site oedema	1	0
Incision site pain	10	0
Infusion related reaction	19	0

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Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Injection related reaction	611	0
Needle fatigue	1	0
Post procedural complication	35	0
Post procedural contusion	2	0
Post procedural discomfort	1	0
Post procedural haematoma	1	0
Post procedural haemorrhage	1	0
Procedural hypertension	1	0
Procedural pain	8	0
Procedural site reaction	1	0
Suture related complication	1	0
<b>Occupational exposures</b>		
Occupational exposure to product	1	0
<b>Off label uses</b>		
Off label use	87	0
<b>Overdoses NEC</b>		
Intentional overdose	13	0
Overdose	58	0
Prescribed overdose	1	0
<b>Pathways and sources of exposure</b>		
Exposure via body fluid	1	0
Exposure via partner	1	0
Exposure via unknown route	1	0
<b>Peripheral nerve injuries</b>		
Brachial plexus injury	2	0
Median nerve injury	2	0
Radial nerve injury	1	0
Sciatic nerve injury	1	0
Ulnar nerve injury	3	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	3	0
Chemical poisoning	1	0
Metal poisoning	2	0
Poisoning	7	0
Systemic toxicity	2	0
Toxicity to various agents	10	0
<b>Product administration errors and issues</b>		
Accidental overdose	4	0
Accidental underdose	2	0
Booster dose missed	1	0
Contraindicated product administered	5	0
Drug administered in wrong device	1	0
Duplicate therapy error	2	0
Expired product administered	26	0
Extra dose administered	10	0
Inappropriate schedule of product administration	135	0
Incomplete course of vaccination	65	0
Incorrect dose administered	13	0
Incorrect product administration duration	2	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	57	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Poor quality product administered	3	0
Product administered at inappropriate site	25	0
Product administered to patient of inappropriate age	31	0
Product administration error	29	0
Product dose omission in error	2	0
Product dose omission issue	40	0
Wrong patient received product	1	0
Wrong product administered	22	0
<b>Product confusion errors and issues</b>		
Product label confusion	1	0
Product name confusion	2	0
Product packaging confusion	1	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	16	0
<b>Product monitoring errors and issues</b>		
Documented hypersensitivity to administered product	1	0
Labelled drug-drug interaction medication error	1	0
Product monitoring error	1	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	10	0
Product prescribing error	5	0
<b>Product selection errors and issues</b>		
Product selection error	3	0
<b>Product storage errors and issues in the product use system</b>		
Intercepted product storage error	1	0
Product storage error	7	0
<b>Product transcribing errors and communication issues</b>		
Product communication issue	2	0
<b>Radiation injuries</b>		
Sunburn	54	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
Kidney rupture	2	0
<b>Reproductive system and breast injuries</b>		
Penile contusion	3	0
Penis injury	2	0
Uterine rupture	1	0
<b>Reproductive tract and breast procedural complications</b>		
Ovarian injury	1	0
Postmastectomy lymphoedema syndrome	1	0
<b>Respiratory tract and thoracic cavity procedural complications</b>		
Pulmonary oil microembolism	2	0
<b>Site specific injuries NEC</b>		
Back injury	7	0
Central nervous system injury	1	0
Face crushing	1	0
Face injury	2	0
Head injury	44	0
Limb crushing injury	9	0
Limb injury	360	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	3	0

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Pharyngeal contusion	3	0
<b>Site specific procedural complications NEC</b>		
Axillary web syndrome	3	0
<b>Skin injuries NEC</b>		
Contusion	3389	0
Hair injury	3	0
Nail injury	1	0
Scar	46	0
Scratch	6	0
Skin abrasion	6	0
Skin injury	25	0
Skin laceration	7	0
Skin pressure mark	1	0
Skin wound	7	0
Subcutaneous haematoma	3	0
<b>Skin procedural complications</b>		
Dermal filler overcorrection	1	0
Recall phenomenon	2	0
<b>Skull fractures, facial bone fractures and dislocations</b>		
Skull fracture	1	0
<b>Spinal cord injuries NEC</b>		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury	5	0
Spinal cord injury sacral	1	0
Spinal cord injury thoracic	1	0
<b>Spinal fractures and dislocations</b>		
Spinal compression fracture	4	0
Spinal fracture	9	0
<b>Stoma complications</b>		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
Stoma site haemorrhage	1	0
Stoma site pain	2	0
Stoma site rash	1	0
<b>Thermal burns</b>		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	4	0
Burn oral cavity	11	0
Burns second degree	2	0
Cold burn	3	0
Thermal burn	56	0
Thermal burns of eye	47	0
<b>Thoracic cage fractures and dislocations</b>		
Rib fracture	1	0
<b>Transplantation complications</b>		
Transplant failure	1	0
<b>Underdoses NEC</b>		
Intentional underdose	1	0
Underdose	10	0
<b>Vaccination related complications</b>		
Adverse event following immunisation	5	0
Post vaccination syndrome	5	0

# Case Series Drug Analysis Print

## Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	109	0
<b>Injuries SOC TOTAL</b>	<b>9435</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal cortex tests</i></b>		
Blood cortisol	1	0
Cortisol decreased	3	0
Cortisol increased	2	0
<b><i>Adrenal medulla tests</i></b>		
Epinephrine increased	1	0
Norepinephrine increased	2	0
<b><i>Auditory and vestibular diagnostic procedures</i></b>		
Acoustic stimulation tests	8	0
Audiogram	1	0
<b><i>Autoimmunity analyses</i></b>		
Anti-sperm antibody	1	0
Antimitochondrial antibody positive	2	0
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody	1	0
Antinuclear antibody positive	3	0
Antiphospholipid antibodies	3	0
Antiphospholipid antibodies positive	4	0
Cold agglutinins positive	2	0
DNA antibody negative	1	0
DNA antibody positive	1	0
Rheumatoid factor	4	0
Rheumatoid factor increased	3	0
Rheumatoid factor negative	1	0
Smooth muscle antibody	1	0
<b><i>Bacteria identification and serology (excl mycobacteria)</i></b>		
Bacterial test	1	0
Staphylococcus test positive	1	0
Streptococcus test positive	1	0
Treponema test positive	1	0
<b><i>Blood counts NEC</i></b>		
Full blood count	21	0
Full blood count abnormal	12	0
Full blood count decreased	3	0
Full blood count increased	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Blood gases	1	0
Blood gases abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid increased	6	0
Blood pH	18	0
Blood pH increased	15	0
Carbon dioxide increased	1	0
Oxygen consumption	2	0
Oxygen saturation	26	0
Oxygen saturation abnormal	3	0
Oxygen saturation decreased	194	0
Oxygen saturation normal	1	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<b><i>Blood grouping and cross-matching analyses</i></b>		
Blood group O	2	0
Blood grouping	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Rhesus antigen negative	1	0
<b>Bone marrow and immune tissue imaging procedures</b>		
Scan lymph nodes	2	0
<b>Carbohydrate tolerance analyses (incl diabetes)</b>		
Blood glucose	20	0
Blood glucose abnormal	22	0
Blood glucose decreased	45	0
Blood glucose fluctuation	35	0
Blood glucose increased	191	0
Glycosylated haemoglobin increased	2	0
<b>Cardiac auscultatory investigations</b>		
Cardiac murmur	39	0
Heart sounds	19	0
Heart sounds abnormal	8	0
<b>Cardiac function diagnostic procedures</b>		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	3	0
Ejection fraction decreased	4	0
Myocardial strain imaging	21	0
Stroke volume decreased	2	0
Stroke volume increased	1	0
Venous pressure jugular increased	1	0
<b>Cardiac imaging procedures</b>		
Magnetic resonance imaging heart	1	0
<b>Cell marker analyses</b>		
Carbohydrate antigen 15-3	1	0
Carcinoembryonic antigen increased	2	0
Prostatic specific antigen decreased	1	0
Prostatic specific antigen increased	4	0
Tumour marker increased	1	0
<b>Central nervous system histopathology procedures</b>		
Biopsy brain	1	0
<b>Central nervous system imaging procedures</b>		
Brain scan abnormal	1	0
Computerised tomogram head	28	0
Magnetic resonance imaging head	47	0
Magnetic resonance imaging head abnormal	1	0
Scan brain	1	0
<b>Cerebrospinal fluid tests (excl microbiology)</b>		
CSF cell count abnormal	1	0
CSF oligoclonal band present	1	0
CSF pressure	4	0
CSF protein increased	1	0
CSF test abnormal	1	0
CSF white blood cell count increased	1	0
Xanthochromia	1	0
<b>Chemistry analyses NEC</b>		
Histamine abnormal	4	0
Histamine level	3	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	13	0

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Serum serotonin increased	1	0
<b>Cholesterol analyses</b>		
Blood cholesterol increased	20	0
Low density lipoprotein	1	0
Low density lipoprotein increased	1	0
Very low density lipoprotein decreased	1	0
<b>Coagulation and bleeding analyses</b>		
ADAMTS13 activity abnormal	1	0
ADAMTS13 activity decreased	1	0
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time abnormal	1	0
Activated partial thromboplastin time prolonged	123	0
Anti factor VIII antibody positive	1	0
Anti-platelet factor 4 antibody positive	1	0
Bleeding time	11	0
Bleeding time abnormal	3	0
Bleeding time prolonged	6	0
Bleeding time shortened	2	0
Blood fibrinogen abnormal	2	0
Blood fibrinogen decreased	7	0
Blood fibrinogen increased	2	0
Blood thromboplastin	1	0
Blood thromboplastin abnormal	1	0
Clot retraction	1	0
Coagulation factor	1	0
Coagulation factor VIII level decreased	6	0
Coagulation test abnormal	1	0
Coagulation time	9	0
Coagulation time prolonged	14	0
Coagulation time shortened	4	0
Fibrin D dimer	1	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	65	0
Heparin-induced thrombocytopenia test positive	1	0
International normalised ratio	3	0
International normalised ratio abnormal	11	0
International normalised ratio decreased	44	0
International normalised ratio fluctuation	5	0
International normalised ratio increased	90	0
Prothrombin level increased	1	0
Prothrombin time	1	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
Thrombin time abnormal	2	0
<b>Digestive enzymes</b>		
Amylase increased	1	0
Lipase increased	1	0
Pancreatic enzymes increased	1	0
<b>ECG investigations</b>		
Cardiac telemetry	1	0
Electrocardiogram	8	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	4	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Electrocardiogram ST segment elevation	7	0
Electrocardiogram ST-T segment abnormal	6	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	21	0
Electrocardiogram change	2	0
Electrocardiogram normal	1	0
Electrocardiogram pacemaker spike	1	0
Exercise electrocardiogram	1	0
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	63	0
<b>Faecal analyses NEC</b>		
Faecal calprotectin	1	0
Faecal calprotectin increased	9	0
Occult blood	1	0
Stool analysis abnormal	2	0
<b>Fertility analyses</b>		
Semen analysis abnormal	1	0
Semen volume decreased	2	0
Sperm concentration	1	0
Spermatozoa abnormal	1	0
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate	1	0
Foetal heart rate abnormal	1	0
<b>Fungus identification and serology</b>		
Fungal test	1	0
<b>Gastrointestinal and abdominal imaging procedures</b>		
Barium swallow	1	0
Computerised tomogram abdomen	4	0
Magnetic resonance imaging abdominal	1	0
Stomach scan	1	0
<b>Gastrointestinal function diagnostic procedures</b>		
Gastric pH	2	0
Gastric pH decreased	2	0
Gastrointestinal stoma output increased	1	0
Swallow study	3	0
<b>Gastrointestinal, pancreatic and APUD hormone analyses</b>		
Blood gastrin	1	0
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin abnormal	1	0
Blood insulin decreased	2	0
Blood insulin increased	3	0
<b>Haematological analyses NEC</b>		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	4	0
Haematology test abnormal	2	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate	1	0
Red blood cell sedimentation rate abnormal	1	0
Red blood cell sedimentation rate increased	12	0
<b>Heart rate and pulse investigations</b>		
Brachial pulse decreased	1	0

## Case Series Drug Analysis Print

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Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Carotid pulse	1	0
Femoral pulse	1	0
Heart rate	1138	0
Heart rate abnormal	67	0
Heart rate decreased	142	0
Heart rate increased	2138	0
Heart rate irregular	271	0
Heart rate variability decreased	1	0
Heart rate variability increased	3	0
Maximum heart rate	8	0
Maximum heart rate decreased	1	0
Maximum heart rate increased	2	0
Orthostatic heart rate response increased	1	0
Popliteal pulse	1	0
Pulse abnormal	30	0
Pulse absent	4	0
Pulse pressure increased	3	0
Pulse waveform abnormal	1	0
Radial pulse	1	0
Sinus rhythm	9	0
<b>Histopathology procedures NEC</b>		
Biopsy	1	0
Smear test	1	0
<b>Imaging procedures NEC</b>		
Computerised tomogram	7	0
Computerised tomogram normal	1	0
Magnetic resonance imaging	2	0
Magnetic resonance imaging abnormal	1	0
Magnetic resonance imaging whole body	1	0
Scan	1	0
Ultrasound scan	1	0
X-ray	1	0
<b>Immunoglobulin analyses</b>		
Blood immunoglobulin A increased	1	0
Blood immunoglobulin E	1	0
Blood immunoglobulin E increased	3	0
Blood immunoglobulin G	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
Immunoglobulins decreased	2	0
<b>Immunology analyses NEC</b>		
Antibody test	5	0
Antibody test abnormal	7	0
Antibody test negative	17	0
Antibody test positive	2	0
Immunology test	13	1
Immunology test normal	1	0
Mast cell degranulation present	1	0
Tryptase increased	1	0
<b>Immunology skin tests NEC</b>		
Allergy alert test	3	0
Skin test positive	7	0
<b>Investigations NEC</b>		

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
APACHE II score	1	0
Blood test	54	0
Blood test abnormal	95	0
Blood test normal	1	0
Laboratory test	1	0
Laboratory test abnormal	1	0
Polymerase chain reaction positive	3	0
Quality of life decreased	3	0
<b>Liver function analyses</b>		
Alanine aminotransferase decreased	1	0
Alanine aminotransferase increased	32	0
Ammonia	1	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase increased	4	0
Bile output	4	0
Blood bilirubin	1	0
Blood bilirubin increased	7	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	16	0
Liver function test	3	0
Liver function test abnormal	56	0
Liver function test increased	17	0
Transaminases increased	12	0
<b>Metabolism tests NEC</b>		
Blood ketone body	10	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	4	0
Brain natriuretic peptide increased	1	0
Ubiquinone	4	0
Ubiquinone decreased	2	0
Urine ketone body present	2	0
<b>Microbiology and serology tests NEC</b>		
Blood culture	2	0
Blood culture negative	1	0
Septic screen	1	0
Serology test	1	0
<b>Mineral and electrolyte analyses</b>		
Blood calcium	2	0
Blood calcium increased	1	0
Blood cyanide	1	0
Blood iron	14	0
Blood iron decreased	35	0
Blood iron increased	5	0
Blood magnesium decreased	3	0
Blood phosphorus abnormal	1	0
Blood phosphorus decreased	7	0
Blood phosphorus increased	4	0
Blood potassium decreased	12	0
Blood potassium increased	9	0
Blood sodium	2	0
Blood sodium decreased	6	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood zinc increased	1	0
Iron binding capacity total decreased	1	0
Serum ferritin	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	7	0
Sweat test	3	0
Transferrin decreased	1	0
Urine copper	2	0
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Bone densitometry	1	0
Discogram abnormal	1	0
Magnetic resonance imaging neck	1	0
Skull X-ray	12	0
X-ray limb	3	0
X-ray limb abnormal	1	0
X-ray of pelvis and hip	2	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Muscle mass percentage	1	0
Swollen joint count	2	0
Swollen joint count increased	4	0
Tender joint count	4	0
<b><i>Mycobacteria identification and serology</i></b>		
Interferon gamma release assay positive	2	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	19	0
Electroencephalogram abnormal	1	0
Electromyogram abnormal	3	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	2	0
Lumbar puncture	20	0
NIH stroke scale	1	0
Nerve conduction studies	1	0
Nerve conduction studies abnormal	2	0
Nerve stimulation test abnormal	1	0
Neurotransmitter level altered	1	0
Sensory level abnormal	1	0
Sleep study normal	1	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Corneal reflex decreased	2	0
Intraocular pressure increased	8	0
Intraocular pressure test	8	0
Pupillary light reflex tests abnormal	1	0
Retinal function test abnormal	1	0
Visual tracking test	1	0
<b><i>Parathyroid analyses</i></b>		
Blood parathyroid hormone decreased	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body height decreased	1	0
Body surface area	3	0
Body surface area decreased	1	0
Body temperature	1043	0
Body temperature abnormal	88	0
Body temperature decreased	141	0

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Body temperature fluctuation	193	0
Body temperature increased	1166	0
Body temperature normal	3	0
Breath sounds	3	0
Breath sounds abnormal	7	0
Dermatologic examination abnormal	1	0
General physical condition abnormal	4	0
Grip strength	13	0
Grip strength decreased	38	0
Head lag	19	0
Lymph node palpable	6	0
Male genital examination abnormal	1	0
Menstruation normal	6	0
Muscle strength abnormal	6	0
Neurological examination	1	0
Neurological examination abnormal	1	0
Neurological examination normal	1	0
Ophthalmological examination	3	0
Ophthalmological examination abnormal	1	0
Palpatory finding abnormal	1	0
Product residue present	3	0
Psoriasis area severity index decreased	1	0
Psoriasis area severity index increased	1	0
Respiratory rate	14	0
Respiratory rate decreased	32	0
Respiratory rate increased	82	0
Skin temperature	179	0
Temperature difference of extremities	9	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	243	0
Weight increased	74	0
<b><i>Pituitary analyses anterior</i></b>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	2	0
Blood growth hormone increased	1	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone	1	0
Blood thyroid stimulating hormone abnormal	1	0
Blood thyroid stimulating hormone decreased	4	0
Blood thyroid stimulating hormone increased	5	0
<b><i>Platelet analyses</i></b>		
Platelet count	5	0
Platelet count abnormal	2	0
Platelet count decreased	350	1
Platelet count increased	7	0
Platelet count normal	1	0
Platelet morphology abnormal	1	0
Plateletcrit	1	0
<b><i>Protein analyses NEC</i></b>		
Blood albumin abnormal	1	0
C-reactive protein	1	0
C-reactive protein abnormal	3	0

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
C-reactive protein decreased	1	0
C-reactive protein increased	44	0
Protein total	2	0
Protein total abnormal	1	0
Protein total increased	2	0
Zinc sulphate turbidity increased	1	0
<b>Red blood cell analyses</b>		
Haematocrit	10	0
Haematocrit decreased	1	0
Haematocrit increased	3	0
Haemoglobin	7	0
Haemoglobin decreased	20	0
Haemoglobin increased	2	0
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	2	0
Red blood cell count	3	0
Red blood cell count decreased	2	0
Red blood cell count increased	1	0
Red blood cell elliptocytes present	1	0
Red blood cell morphology abnormal	1	0
Red blood cell target cells present	1	0
<b>Renal function analyses</b>		
Blood creatine increased	1	0
Blood creatinine abnormal	1	0
Blood creatinine decreased	2	0
Blood creatinine increased	3	0
Blood urea	7	0
Blood urea increased	1	0
Glomerular filtration rate decreased	6	0
<b>Reproductive hormone analyses</b>		
17 ketosteroids urine decreased	1	0
Anti-Muellerian hormone level decreased	4	0
Blood oestrogen	2	0
Blood oestrogen decreased	1	0
Blood oestrogen increased	1	0
Blood testosterone decreased	2	0
Blood testosterone increased	1	0
Dihydrotestosterone decreased	1	0
False negative pregnancy test	4	0
Female sex hormone level	1	0
Human chorionic gonadotropin decreased	1	0
Oestradiol	2	0
Oestradiol decreased	1	0
Oestriol	1	0
Pregnancy test	17	0
Pregnancy test false positive	2	0
Pregnancy test negative	2	0
Progesterone decreased	1	0
Reproductive hormone	1	0
<b>Reproductive organ and breast histopathology procedures</b>		
Biopsy breast	1	0
Biopsy vagina	1	0
Smear cervix	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Reproductive organ and breast imaging procedures</i></b>		
Mammogram	1	0
Ultrasound scan vagina normal	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume	2	0
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	14	0
Forced expiratory volume normal	1	0
Forced vital capacity decreased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate abnormal	1	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	4	0
Pulmonary function test decreased	6	0
Slow vital capacity	1	0
Total lung capacity decreased	6	0
<b><i>Respiratory tract and thoracic histopathology procedures</i></b>		
Sputum abnormal	3	0
<b><i>Respiratory tract and thoracic imaging procedures</i></b>		
Chest X-ray	21	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0
Ventilation/perfusion scan	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	8	0
Muscle enzyme increased	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	1	0
Troponin	2	0
Troponin I increased	3	0
Troponin T	1	0
Troponin T increased	1	0
Troponin increased	19	0
<b><i>Skin histopathology procedures</i></b>		
Biopsy skin	1	0
<b><i>Special sense investigations NEC</i></b>		
Olfactory test	1	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	17	0
Analgesic drug level increased	1	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	3	0
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
Antidepressant drug level decreased	1	0
Drug level increased	3	0
<b><i>Thyroid analyses</i></b>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroid hormones decreased	1	0
Thyroxine	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Thyroxine abnormal	1	0
Thyroxine increased	2	0
Tri-iodothyronine decreased	7	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood alkaline phosphatase decreased	1	0
Blood alkaline phosphatase increased	3	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Lactate dehydrogenase urine increased	1	0
<b><i>Toxicology laboratory analyses</i></b>		
Blood aluminium	1	0
Blood arsenic normal	1	0
Blood cannabinoids	1	0
Blood carbon monoxide increased	3	0
Blood lead	1	0
Drug screen positive	4	0
Heavy metal test	1	0
<b><i>Triglyceride analyses</i></b>		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine	39	0
Blood urine present	93	0
Cells in urine	2	0
Crystal urine	4	0
Glucose urine	1	0
Haemoglobin urine	1	0
Medication crystals in urine present	1	0
Protein urine	3	0
Protein urine present	2	0
Red blood cells urine	1	0
Urea urine increased	1	0
Urine analysis	1	0
Urine analysis abnormal	17	0
Urine analysis normal	3	0
White blood cells urine positive	1	0
pH urine	10	0
pH urine decreased	2	0
pH urine increased	3	0
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output	49	0
Urine output decreased	18	0
Urine output increased	11	0
<b><i>Urinary tract histopathology procedures</i></b>		
Biopsy kidney	1	0
<b><i>Urinary tract imaging procedures</i></b>		
Cystoscopy	3	0
Ultrasound kidney	1	0
<b><i>Vascular auscultatory investigations</i></b>		
Abdominal bruit	1	0
Aortic bruit	1	0
Carotid bruit	1	0
<b><i>Vascular imaging procedures NEC</i></b>		

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Arteriogram carotid	1	0
Venogram	2	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	17	0
Blood pressure decreased	104	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	5	0
Blood pressure difference of extremities	1	0
Blood pressure increased	349	0
Blood pressure measurement	115	0
Blood pressure normal	5	0
Blood pressure systolic	1	0
Blood pressure systolic abnormal	1	0
Blood pressure systolic increased	5	0
Capillary nail refill test	1	0
Pulmonary arterial pressure abnormal	1	0
<b>Virus identification and serology</b>		
Blood HIV RNA increased	1	0
Coronavirus test	43	0
Cytomegalovirus test	1	0
Epstein-Barr virus antibody positive	1	0
HIV antibody negative	2	0
Hepatitis B core antibody positive	1	0
Hepatitis B surface antibody positive	1	0
Herpes virus test	1	0
Human papilloma virus test positive	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 RNA	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	34	0
SARS-CoV-2 antibody test positive	11	0
SARS-CoV-2 test	30	0
SARS-CoV-2 test false negative	5	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	19	0
SARS-CoV-2 test positive	116	0
Varicella virus test positive	1	0
Viral load	1	0
Viral test	4	0
Viral test positive	1	0
<b>Vitamin analyses</b>		
Blood folate	3	0
Blood folate abnormal	1	0
Blood folate decreased	13	0
Vitamin B12	2	0
Vitamin B12 abnormal	3	0
Vitamin B12 decreased	6	0
Vitamin D	3	0
Vitamin D decreased	7	0
Vitamin D increased	1	0
Vitamin E decreased	1	0
<b>Water and electrolyte analyses NEC</b>		

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood electrolytes decreased	2	0
Blood osmolarity	1	0
Volume blood	7	0
<b>White blood cell analyses</b>		
CD4 lymphocytes decreased	1	0
Eosinophil count	1	0
Eosinophil count abnormal	2	0
Eosinophil count decreased	1	0
Eosinophil count increased	7	0
Lymphocyte count	3	0
Lymphocyte count abnormal	1	0
Lymphocyte count decreased	6	0
Lymphocyte count increased	3	0
Monocyte count increased	1	0
Mononuclear cell count abnormal	1	0
Natural killer cell count increased	1	0
Neutrophil count	4	0
Neutrophil count abnormal	1	0
Neutrophil count decreased	20	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	21	0
White blood cell count decreased	36	0
White blood cell count increased	14	0
White blood cell count normal	1	0
<b>Investigations SOC TOTAL</b>	<b>11533</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	38	0
Decreased appetite	6482	0
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	26	0
Food refusal	42	0
Hyperphagia	10	0
Hypophagia	38	0
Increased appetite	61	0
Salt craving	4	0
<b><i>Calcium metabolism disorders</i></b>		
Hypercalcaemia	2	0
Hypocalcaemia	8	0
Tetany	1	0
<b><i>Copper metabolism disorders</i></b>		
Copper deficiency	1	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Diabetes mellitus	121	0
Diabetes mellitus inadequate control	29	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Steroid diabetes	1	0
Type 1 diabetes mellitus	26	0
Type 2 diabetes mellitus	5	0
<b><i>Diabetic complications NEC</i></b>		
Diabetic ketoacidosis	42	2
Diabetic ketosis	5	0
Euglycaemic diabetic ketoacidosis	1	0
<b><i>Diabetic complications neurological</i></b>		
Hyperglycaemic hyperosmolar nonketotic syndrome	2	0
<b><i>Disorders of purine metabolism</i></b>		
Gout	186	0
<b><i>Electrolyte imbalance NEC</i></b>		
Electrolyte imbalance	4	0
Fluid imbalance	1	0
Hyperosmolar state	1	0
<b><i>Fat soluble vitamin deficiencies and disorders</i></b>		
Vitamin D deficiency	17	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	10	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	16	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Alcohol intolerance	14	0
Dairy intolerance	6	0
Food intolerance	26	0
Gluten sensitivity	6	0
Histamine intolerance	4	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal loss of weight	84	0
Abnormal weight gain	40	0
Cachexia	2	0

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Feeding disorder	219	0
Food aversion	57	0
Neonatal insufficient breast milk syndrome	4	0
Obesity	1	0
Overfeeding of infant	1	0
Overweight	2	0
Poor feeding infant	17	0
Starvation	1	0
Underweight	2	0
Weight loss poor	4	0
<b>Hyperglycaemic conditions NEC</b>		
Glucose tolerance impaired	4	0
Hyperglycaemia	133	0
Insulin resistance	9	0
Metabolic syndrome	1	0
<b>Hyperlipidaemias NEC</b>		
Hyperlipidaemia	4	0
<b>Hypoglycaemic conditions NEC</b>		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	105	0
Hypoglycaemia unawareness	2	0
Postprandial hypoglycaemia	3	0
<b>Iron deficiencies</b>		
Iron deficiency	18	0
<b>Iron excess</b>		
Iron overload	1	0
<b>Lipid metabolism and deposit disorders NEC</b>		
Lipoedema	1	0
<b>Magnesium metabolism disorders</b>		
Hypomagnesaemia	1	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Hyperlactacidaemia	2	0
Ketoacidosis	1	0
Ketosis	6	0
Lactic acidosis	3	0
Metabolic acidosis	13	0
<b>Metabolic disorders NEC</b>		
Hypometabolism	1	0
Metabolic disorder	2	0
<b>Mixed acid-base disorders</b>		
Acidosis	5	0
<b>Phosphorus metabolism disorders</b>		
Hypophosphataemia	2	0
<b>Potassium imbalance</b>		
Hyperkalaemia	6	0
Hypokalaemia	6	0
Hypokalaemic syndrome	3	0
<b>Protein metabolism disorders NEC</b>		
Hypoalbuminaemia	1	0
<b>Sodium imbalance</b>		
Hypernatraemia	3	0
Hyponatraemia	29	0
Hyponatraemic syndrome	4	1

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	9	0
<i>Total fluid volume decreased</i>		
Dehydration	698	0
Hypovolaemia	2	0
<i>Total fluid volume increased</i>		
Fluid retention	98	0
Hypervolaemia	13	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	4	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	13	0
Vitamin B complex deficiency	2	0
Vitamin B12 deficiency	17	0
<b>Metabolic disorders SOC TOTAL</b>	<b>8901</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	626	0
Arthritis enteropathic	2	0
Arthropathy	42	0
Autoimmune arthritis	12	0
Haemarthrosis	9	0
Oligoarthritis	1	0
Palindromic rheumatism	7	0
Polyarthritis	20	0
Rheumatic fever	8	0
Sacroiliitis	4	0
Seronegative arthritis	3	0
Sympathetic posterior cervical syndrome	1	0
<b><i>Bone disorders NEC</i></b>		
Bone disorder	3	0
Bone erosion	1	0
Bone loss	2	0
Exostosis	2	0
Jaw disorder	5	0
Medial tibial stress syndrome	9	0
Osteitis	12	0
Osteonecrosis	4	0
Osteonecrosis of jaw	4	0
Osteosclerosis	2	0
Spinal disorder	2	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	1102	0
Bone swelling	9	0
Coccydynia	8	0
Pain in jaw	631	0
Pubic pain	1	0
Spinal pain	270	0
<b><i>Bursal disorders</i></b>		
Bursitis	228	0
<b><i>Cartilage disorders</i></b>		
Chondritis	1	0
Chondropathy	2	0
Costochondritis	94	0
Osteochondrosis	1	0
Polychondritis	1	0
<b><i>Connective tissue disorders NEC</i></b>		
Collagen disorder	2	0
Connective tissue disorder	4	0
Eosinophilic fasciitis	1	0
Mixed connective tissue disease	1	0
Morphoea	3	0
Polymyalgia rheumatica	104	0
Reynold's syndrome	6	0
Scleroderma	4	0
Sjogren's syndrome	4	0
Systemic scleroderma	1	0
<b><i>Crystal arthropathic disorders</i></b>		
Chondrocalcinosis pyrophosphate	4	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Gouty tophus	1	0
<b>Epiphyseal disorders</b>		
Epiphyses premature fusion	1	0
<b>Extremity deformities</b>		
Acquired claw toe	1	0
Elbow deformity	1	0
Finger deformity	4	0
Foot deformity	7	0
Hand deformity	4	0
Knee deformity	1	0
Limb deformity	10	0
Wrist deformity	2	0
<b>Fractures NEC</b>		
Osteoporotic fracture	3	0
Pathological fracture	1	0
<b>Intervertebral disc disorders NEC</b>		
Intervertebral disc degeneration	3	0
Intervertebral disc disorder	1	0
Intervertebral disc protrusion	11	0
<b>Joint related disorders NEC</b>		
Ankle impingement	1	0
Femoroacetabular impingement	2	0
Hypermobility syndrome	3	0
Joint adhesion	1	0
Joint ankylosis	2	0
Joint contracture	1	0
Joint instability	3	0
Joint laxity	6	0
Joint lock	61	0
Ligament laxity	1	0
Patellofemoral pain syndrome	7	0
Periarthritis	520	0
Rotator cuff syndrome	99	0
Temporomandibular joint syndrome	22	0
<b>Joint related signs and symptoms</b>		
Arthralgia	23373	0
Jaw clicking	5	0
Joint effusion	11	0
Joint noise	52	0
Joint range of motion decreased	6	0
Joint stiffness	486	0
Joint swelling	1093	0
Joint vibration	6	0
Joint warmth	39	0
Loose body in joint	1	0
<b>Ligament disorders</b>		
Ligament pain	11	0
<b>Lupus erythematosus (incl subtypes)</b>		
Lupus-like syndrome	2	0
Systemic lupus erythematosus	40	0
<b>Metabolic bone disorders</b>		
Dwarfism	1	0
Osteopenia	2	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Osteoporosis	12	0
<b>Muscle infections and inflammations</b>		
Autoimmune myositis	1	0
Myositis	56	0
Polymyositis	5	0
<b>Muscle pains</b>		
Fibromyalgia	313	0
Myalgia	26981	0
Myalgia intercostal	3	0
Myofascial pain syndrome	27	0
<b>Muscle related signs and symptoms NEC</b>		
Haematoma muscle	4	0
Muscle atrophy	40	0
Muscle discomfort	22	0
Muscle disorder	13	0
Muscle fatigue	1023	0
Muscle haemorrhage	5	0
Muscle hypertrophy	1	0
Muscle mass	12	0
Muscle oedema	3	0
Muscle spasms	3605	0
Muscle swelling	34	0
Muscle tightness	200	0
Muscle twitching	617	0
<b>Muscle tone abnormalities</b>		
Muscle rigidity	53	0
Nuchal rigidity	18	0
Torticollis	14	0
Trismus	57	0
<b>Muscle weakness conditions</b>		
Muscular weakness	2290	0
Sarcopenia	1	0
<b>Musculoskeletal and connective tissue conditions NEC</b>		
Back disorder	4	0
Extremity contracture	2	0
Infantile back arching	1	0
Limb mass	20	0
Mandibular mass	1	0
Mastication disorder	9	0
Mobility decreased	179	0
Muscle contracture	6	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	2428	0
Pelvic misalignment	1	0
Posture abnormal	3	0
Somatic dysfunction	1	0
Weight bearing difficulty	13	0
Winged scapula	2	0
<b>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</b>		
Facial asymmetry	3	0
Head deformity	1	0
<b>Musculoskeletal and connective tissue infections and inflammations NEC</b>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Connective tissue inflammation	4	0
Dactylitis	3	0
Dupuytren's contracture	5	0
Fasciitis	1	0
Plantar fasciitis	14	0
<b>Musculoskeletal and connective tissue pain and discomfort</b>		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5960	0
Flank pain	96	0
Growing pains	8	0
Limb discomfort	2405	0
Musculoskeletal chest pain	428	0
Musculoskeletal discomfort	162	0
Musculoskeletal pain	168	0
Neck pain	3180	0
Pain in extremity	22544	0
Rheumatic disorder	32	0
Sacral pain	7	0
<b>Myopathies</b>		
Compartment syndrome	6	0
Muscle necrosis	1	0
Myopathy	6	0
Rhabdomyolysis	10	1
<b>Osteoarthropathies</b>		
Nodal osteoarthritis	1	0
Osteoarthritis	105	0
Spinal osteoarthritis	10	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	31	0
<b>Rheumatoid arthropathies</b>		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	210	0
Rheumatoid nodule	1	0
Still's disease	6	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	87	0
Clubbing	1	0
Fistula	3	0
Groin pain	235	0
Neck mass	26	0
Soft tissue disorder	3	0
Soft tissue mass	3	0
Soft tissue swelling	7	0
<b>Spine and neck deformities</b>		
Kyphosis	6	0
Scoliosis	4	0
Spinal stenosis	3	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	33	0
Arthritis reactive	66	0
Axial spondyloarthritis	2	0
Spondylitis	7	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Spondyloarthropathy	3	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	16	0
Synovitis	20	0
<b><i>Tendon disorders</i></b>		
Enthesopathy	1	0
Tendon discomfort	4	0
Tendon disorder	10	0
Tendon pain	49	0
Tendon sheath disorder	1	0
Tendonitis	108	0
Tenosynovitis	3	0
Tenosynovitis stenosaurs	4	0
Trigger finger	36	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>103407</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<b><i>Anal canal neoplasms malignant</i></b>		
Anal cancer	1	0
<b><i>Anaplastic large cell lymphomas T- and null-cell types</i></b>		
T-cell lymphoma	1	1
<b><i>Aural neoplasms benign</i></b>		
Benign ear neoplasm	1	0
<b><i>B-cell lymphomas NEC</i></b>		
B-cell lymphoma	2	0
Follicular lymphoma	2	0
<b><i>Bile duct neoplasms malignant</i></b>		
Bile duct cancer	1	0
Cholangiocarcinoma	1	0
Cholangiosarcoma	1	0
<b><i>Bladder neoplasms malignant</i></b>		
Bladder cancer	1	0
<b><i>Bone neoplasms malignant (excl sarcomas)</i></b>		
Bone cancer	2	0
<b><i>Breast and nipple neoplasms benign</i></b>		
Benign breast neoplasm	3	0
Fibroadenoma of breast	1	0
<b><i>Breast and nipple neoplasms malignant</i></b>		
Breast cancer	55	0
Breast cancer female	1	0
Breast cancer in situ	1	0
Breast cancer male	3	0
Breast cancer metastatic	1	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Breast cancer stage IV	1	0
Intraductal proliferative breast lesion	1	0
<b><i>Cardiovascular neoplasms benign</i></b>		
Haemangioma	7	0
<b><i>Central nervous system neoplasms malignant NEC</i></b>		
Brain cancer metastatic	2	0
Brain neoplasm malignant	3	0
<b><i>Cervix neoplasms benign</i></b>		
Cervix warts	1	0
<b><i>Cervix neoplasms malignant</i></b>		
Cervix carcinoma	3	0
<b><i>Colorectal neoplasms malignant</i></b>		
Colon cancer	2	0
Colorectal cancer	3	0
<b><i>Endocrine neoplasms benign NEC</i></b>		
Pituitary tumour benign	2	0
<b><i>Endocrine neoplasms malignant and unspecified NEC</i></b>		
Neuroendocrine tumour	1	0
<b><i>Endometrial neoplasms malignant</i></b>		
Clear cell endometrial carcinoma	1	0
Endometrial cancer	2	0
<b><i>Gastrointestinal neoplasms benign NEC</i></b>		
Gastrointestinal tract adenoma	1	0
<b><i>Gastrointestinal neoplasms malignant NEC</i></b>		
Gastrointestinal carcinoma	8	0

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Reaction Name	Total	Fatal
<b>Neoplasms</b> <span style="float: right;">Neoplasms cont'd</span>		
<i><b>Glial tumours malignant</b></i>		
Glioblastoma	4	0
Glioblastoma multiforme	1	0
<i><b>Haematologic neoplasms NEC</b></i>		
Benign lymph node neoplasm	1	0
Haematological malignancy	2	0
Systemic mastocytosis	1	0
<i><b>Hepatic neoplasms malignant</b></i>		
Hepatocellular carcinoma	4	0
<i><b>Hepatobiliary neoplasms malignancy unspecified</b></i>		
Hepatic neoplasm	1	0
<i><b>Hepatoblastomas</b></i>		
Hepatoblastoma	1	0
<i><b>Hodgkin's disease NEC</b></i>		
Hodgkin's disease	2	0
<i><b>Leiomyosarcomas</b></i>		
Pleomorphic leiomyosarcoma	1	0
<i><b>Leukaemias NEC</b></i>		
Leukaemia	4	0
Leukaemia recurrent	1	0
<i><b>Leukaemias acute myeloid</b></i>		
Acute myeloid leukaemia	4	1
<i><b>Leukaemias chronic lymphocytic</b></i>		
Chronic lymphocytic leukaemia	6	0
<i><b>Leukaemias chronic myeloid</b></i>		
Chronic myeloid leukaemia	1	0
<i><b>Leukaemias myeloid NEC</b></i>		
Myeloid leukaemia	1	0
<i><b>Lip and oral cavity neoplasms benign</b></i>		
Papillary cystadenoma lymphomatosum	1	0
<i><b>Lip and oral cavity neoplasms malignant</b></i>		
Lip and/or oral cavity cancer	1	0
Lip neoplasm malignant stage unspecified	1	0
Squamous cell carcinoma of the oral cavity	2	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	21	0
<i><b>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</b></i>		
Epstein Barr virus positive mucocutaneous ulcer	1	0
Histiocytic necrotising lymphadenitis	1	0
Lymphoproliferative disorder	1	0
Lymphoproliferative disorder in remission	1	0
<i><b>Mediastinal neoplasms malignancy unspecified NEC</b></i>		
Good syndrome	4	0
<i><b>Metastases to specified sites</b></i>		
Metastases to bone	2	0
Metastases to central nervous system	1	1
Metastases to liver	1	0
Metastases to lung	1	1
<i><b>Metastases to unknown and unspecified sites</b></i>		
Metastasis	4	1
<i><b>Myelodysplastic syndromes</b></i>		
Myelodysplastic syndrome	1	0
<i><b>Myeloproliferative disorders (excl leukaemias)</b></i>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Essential thrombocythaemia	2	0
<b>Neoplasms benign site unspecified NEC</b>		
Fibroma	1	0
<b>Neoplasms malignant site unspecified NEC</b>		
Adenocarcinoma	2	0
Malignant neoplasm progression	1	0
Metastatic neoplasm	3	0
Neoplasm malignant	13	2
Recurrent cancer	1	0
Squamous cell carcinoma	4	0
<b>Neoplasms unspecified malignancy and site unspecified NEC</b>		
Neoplasm	1	0
Neoplasm progression	1	0
Neoplasm recurrence	9	0
<b>Nervous system neoplasms unspecified malignancy NEC</b>		
Brain neoplasm	10	3
Meningioma	6	0
Schwannoma	1	0
<b>Neuromas</b>		
Acoustic neuroma	6	0
<b>Non-Hodgkin's lymphomas NEC</b>		
Cutaneous lymphoma	1	0
Non-Hodgkin's lymphoma	2	1
<b>Non-small cell neoplasms malignant of the respiratory tract cell type specified</b>		
Lung adenocarcinoma	1	1
<b>Ocular neoplasms benign</b>		
Eye naevus	4	0
<b>Oesophageal neoplasms malignant</b>		
Oesophageal cancer metastatic	6	0
Oesophageal carcinoma	4	0
Oesophageal squamous cell carcinoma	1	0
<b>Oncologic complications and emergencies</b>		
Cancer fatigue	4	0
Cancer pain	2	0
Intracranial tumour haemorrhage	1	0
<b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b>		
Tonsil cancer	4	0
<b>Ovarian neoplasms malignant (excl germ cell)</b>		
Ovarian cancer	10	0
Ovarian cancer recurrent	2	0
Ovarian cancer stage IV	1	0
<b>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</b>		
Pancreatic carcinoma	6	0
Pancreatic carcinoma metastatic	1	0
<b>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</b>		
Nasal cavity cancer	1	0
<b>Penile neoplasms malignant</b>		
Penile cancer	1	0
<b>Plasma cell myelomas</b>		
Plasma cell myeloma	3	0
Plasmacytoma	1	0

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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
<b><i>Plasma cell neoplasms NEC</i></b>		
Hypergammaglobulinaemia benign monoclonal	3	0
<b><i>Prostatic neoplasms malignant</i></b>		
Prostate cancer	8	0
<b><i>Renal neoplasms malignant</i></b>		
Clear cell renal cell carcinoma	2	0
Metastatic renal cell carcinoma	1	0
Renal cancer	2	0
<b><i>Reproductive neoplasms female benign NEC</i></b>		
Benign hydatidiform mole	1	0
<b><i>Reproductive neoplasms male benign NEC</i></b>		
Testicle adenoma	2	0
<b><i>Respiratory tract and pleural neoplasms malignancy unspecified NEC</i></b>		
Maxillofacial sinus neoplasm	1	0
<b><i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i></b>		
Bronchial carcinoma	4	0
Lung cancer metastatic	1	0
Lung neoplasm malignant	15	0
Throat cancer	1	0
<b><i>Respiratory tract small cell carcinomas</i></b>		
Small cell lung cancer	1	0
<b><i>Salivary gland neoplasms malignant</i></b>		
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
<b><i>Skin melanomas (excl ocular)</i></b>		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	4	0
Malignant melanoma in situ	3	0
Metastatic malignant melanoma	1	0
<b><i>Skin neoplasms benign</i></b>		
Acrochordon	7	0
Anogenital warts	4	0
Haemangioma of skin	18	0
Melanocytic naevus	5	0
Seborrhoeic keratosis	2	0
Skin papilloma	31	0
<b><i>Skin neoplasms malignant and unspecified (excl melanoma)</i></b>		
Basal cell carcinoma	6	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	9	0
Squamous cell carcinoma of skin	1	0
<b><i>Soft tissue neoplasms benign NEC</i></b>		
Knuckle pads	1	0
Lipoma	10	0
<b><i>Thyroid neoplasms benign</i></b>		
Benign neoplasm of thyroid gland	1	0
Thyroid adenoma	1	0
<b><i>Uterine neoplasms benign</i></b>		
Uterine leiomyoma	20	0
<b><i>Uterine neoplasms malignant NEC</i></b>		
Uterine cancer	4	0

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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
<i>Vulval neoplasms malignant</i>		
Squamous cell carcinoma of the vulva	1	0
Vulval cancer	1	0
<b>Neoplasms SOC TOTAL</b>	<b>493</b>	<b>12</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	35	0
Extensor plantar response	3	0
Hyperreflexia	9	0
Hyporeflexia	23	0
Poor sucking reflex	4	0
Reflexes abnormal	1	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	25	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	42	0
<i><b>Acute polyneuropathies</b></i>		
Acute motor axonal neuropathy	6	0
Acute polyneuropathy	3	0
Guillain-Barre syndrome	483	5
Miller Fisher syndrome	28	0
Subacute inflammatory demyelinating polyneuropathy	4	0
<i><b>Alzheimer's disease (incl subtypes)</b></i>		
Dementia Alzheimer's type	1	0
Mixed dementia	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Autonomic nervous system imbalance	24	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	8	0
<i><b>Central nervous system aneurysms and dissections</b></i>		
Carotid artery aneurysm	2	0
Carotid artery dissection	1	0
Intracranial aneurysm	6	1
Vertebral artery dissection	3	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Basal ganglia haemorrhage	3	0
Basal ganglia stroke	1	0
Basilar artery occlusion	1	0
Basilar artery thrombosis	4	1
Brain stem embolism	1	1
Brain stem haemorrhage	5	1
Brain stem infarction	2	2
Brain stem stroke	8	2
Brain stem thrombosis	1	0
Carotid artery occlusion	3	0
Carotid artery thrombosis	11	0
Cerebellar haemorrhage	5	0
Cerebellar infarction	6	0
Cerebellar stroke	11	0
Cerebral artery embolism	12	0
Cerebral artery occlusion	4	0
Cerebral artery thrombosis	16	0
Cerebral haematoma	14	1
Cerebral haemorrhage	190	51
Cerebral infarction	98	5
Cerebral ischaemia	4	0
Cerebral thrombosis	41	4

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Cerebral vascular occlusion	2	0
Cerebrovascular accident	1313	51
Embolic stroke	21	1
Haemorrhage intracranial	58	15
Haemorrhagic cerebral infarction	3	1
Haemorrhagic stroke	47	7
Haemorrhagic transformation stroke	8	3
Internal capsule infarction	1	0
Intracranial haematoma	8	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	3	0
Ischaemic stroke	161	7
Lacunar infarction	6	0
Lacunar stroke	28	0
Perinatal stroke	1	0
Pseudostroke	2	0
Spinal cord haematoma	1	0
Spinal cord infarction	1	0
Spinal stroke	4	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	118	7
Thalamic infarction	1	0
Thalamus haemorrhage	9	0
Thrombotic stroke	16	0
Vertebral artery occlusion	1	0
Vertebral artery thrombosis	1	0
<b>Central nervous system inflammatory disorders NEC</b>		
Arachnoiditis	4	0
Central nervous system inflammation	15	0
Neurosarcoidosis	4	0
<b>Central nervous system vascular disorders NEC</b>		
Brain hypoxia	1	0
Brain stem microhaemorrhage	1	0
Carotid arteriosclerosis	1	0
Carotid artery stenosis	4	0
Central nervous system vasculitis	3	0
Cerebral amyloid angiopathy	5	0
Cerebral arteriosclerosis	2	0
Cerebral arteritis	1	0
Cerebral congestion	4	0
Cerebral microangiopathy	1	0
Cerebral microhaemorrhage	4	0
Cerebral small vessel ischaemic disease	3	0
Cerebral vasoconstriction	2	0
Cerebrovascular disorder	4	0
Cerebrovascular insufficiency	1	0
Dural arteriovenous fistula	1	0
Internal carotid artery deformity	1	0
Reversible cerebral vasoconstriction syndrome	4	0
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	214	23
Cerebral venous thrombosis	51	5
Superior sagittal sinus thrombosis	33	3

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Transverse sinus thrombosis	8	0
<b>Cervical spinal cord and nerve root disorders</b>		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	7	0
<b>Choreiform movements</b>		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
<b>Chronic polyneuropathies</b>		
Chronic inflammatory demyelinating polyradiculoneuropathy	10	0
Demyelinating polyneuropathy	12	0
Diabetic neuropathy	2	0
Polyneuropathy chronic	2	0
<b>Coma states</b>		
Coma	24	0
Diabetic coma	3	0
Hypoglycaemic coma	2	0
<b>Coordination and balance disturbances</b>		
Ataxia	53	0
Balance disorder	987	0
Cerebellar ataxia	5	0
Cerebellar syndrome	2	0
Coordination abnormal	139	0
Dysdiadochokinesis	1	0
Dysstasia	124	0
Hand-eye coordination impaired	2	0
Nystagmus	24	0
<b>Cortical dysfunction NEC</b>		
Agraphia	1	0
Alexia	7	0
Aphasia	184	0
Apraxia	4	0
Dysgraphia	8	0
Dyslexia	2	0
Dyspraxia	8	0
Neurologic neglect syndrome	3	0
Sensory processing disorder	1	0
Visuospatial deficit	2	0
<b>Cranial nerve disorders NEC</b>		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Neurovascular conflict	1	0
Paresis cranial nerve	2	0
<b>Dementia (excl Alzheimer's type)</b>		
Dementia	34	0
Dementia with Lewy bodies	1	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	5	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	16	0
Clinically isolated syndrome	4	0
Demyelination	28	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Neuromyelitis optica spectrum disorder	5	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	21	0
Consciousness fluctuating	4	0
Depressed level of consciousness	93	0
Hypoglycaemic unconsciousness	1	0
Lethargy	4985	0
Loss of consciousness	1120	0
Postictal state	1	0
Sedation	18	0
Somnolence	1985	0
Stupor	9	0
Syncope	2611	0
<b>Disturbances in sleep phase rhythm</b>		
Advanced sleep phase	1	0
Circadian rhythm sleep disorder	6	0
Delayed sleep phase	1	0
Irregular sleep phase	4	0
Irregular sleep wake rhythm disorder	1	0
Non-24-hour sleep-wake disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	10	0
Akinesia	1	0
Ballismus	1	0
Bradykinesia	35	0
Clumsiness	55	0
Dyskinesia	125	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	22	0
Hyperkinesia	27	0
Hypokinesia	106	0
Meige's syndrome	1	0
Motor dysfunction	21	0
Movement disorder	115	0
Psychomotor hyperactivity	40	0
Tardive dyskinesia	1	0
<b>Dystonias</b>		
Dystonia	22	0
Dystonic tremor	3	0
Opisthotonus	4	0
Writer's cramp	1	0
<b>Encephalitis NEC</b>		
Bickerstaff's encephalitis	1	0
Encephalitis autoimmune	4	0
Limbic encephalitis	1	0
Noninfective encephalitis	13	0
<b>Encephalopathies NEC</b>		
Autoimmune encephalopathy	6	1
Encephalopathy	10	0
Hypertensive encephalopathy	1	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	3	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Encephalopathies toxic and metabolic</i></b>		
Hepatic encephalopathy	2	0
<b><i>Eye movement disorders</i></b>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IIIrd nerve paresis	1	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	2	0
VIth nerve paralysis	9	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	618	0
Facial nerve disorder	9	0
Facial paralysis	365	0
Facial paresis	177	0
Facial spasm	46	0
Oculofacial paralysis	1	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	105	0
<b><i>Glossopharyngeal nerve disorders</i></b>		
Glossopharyngeal neuralgia	1	0
<b><i>Headaches NEC</i></b>		
Cervicogenic headache	6	0
Chronic paroxysmal hemicrania	1	0
Cluster headache	765	0
Cold-stimulus headache	91	0
Drug withdrawal headache	17	0
Exertional headache	12	0
External compression headache	5	0
Headache	81622	0
Medication overuse headache	19	0
New daily persistent headache	20	0
Occipital neuralgia	27	0
Ophthalmoplegic migraine	1	0
Post-traumatic headache	3	0
Primary cough headache	2	0
Primary headache associated with sexual activity	13	0
Sinus headache	961	0
Tension headache	1534	0
Thunderclap headache	50	0
Vascular headache	85	0
<b><i>Hydrocephalic conditions</i></b>		
Hydrocephalus	18	1
<b><i>Hypoglossal nerve disorders</i></b>		
Tongue paralysis	6	0
<b><i>Increased intracranial pressure disorders</i></b>		
Brain compression	4	0
Brain oedema	37	2
Cerebrospinal fluid circulation disorder	6	0
Cytotoxic oedema	1	0
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	34	0
Vasogenic cerebral oedema	1	0
<b><i>Intellectual disabilities</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Intellectual disability	11	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Lumbar radiculopathy	5	0
Sciatica	236	0
<b>Memory loss (excl dementia)</b>		
Amnesia	435	0
Memory impairment	404	0
Retrograde amnesia	1	0
Transient global amnesia	25	0
<b>Meningitis NEC</b>		
Meningitis noninfective	1	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	213	0
Disturbance in attention	763	0
Judgement impaired	5	0
Mental impairment	143	0
<b>Migraine headaches</b>		
Basilar migraine	5	0
Hemiplegic migraine	51	0
Migraine	7737	0
Migraine with aura	400	0
Migraine without aura	48	0
Ophthalmic migraine	14	0
Retinal migraine	90	0
Status migrainosus	5	0
Typical aura without headache	19	0
Vestibular migraine	40	0
<b>Mixed cranial nerve disorders</b>		
Bulbar palsy	3	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	44	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Long thoracic nerve palsy	2	0
Meralgia paraesthetica	3	0
Mononeuritis	4	0
Mononeuropathy	3	0
Nerve compression	58	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	19	0
Piriformis syndrome	4	0
Radial nerve palsy	2	0
Sciatic nerve neuropathy	5	0
Ulnar nerve palsy	3	0
Ulnar neuritis	4	0
Ulnar tunnel syndrome	1	0
<b>Motor neurone diseases</b>		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	1	0
Motor neurone disease	6	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	6	0
Multiple sclerosis	60	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Multiple sclerosis pseudo relapse	2	0
Multiple sclerosis relapse	61	0
Progressive multiple sclerosis	1	0
Relapsing multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	0
Uhthoff's phenomenon	2	0
<b>Muscle tone abnormal</b>		
Drop attacks	2	0
Hypertonia	5	0
Hypotonia	42	0
Serotonin syndrome	1	0
Stiff leg syndrome	10	0
Stiff person syndrome	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	107	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	1	0
Hypersomnia	230	0
Narcolepsy	22	0
<b>Nervous system cysts and polyps</b>		
Arachnoid cyst	1	0
Pineal gland cyst	1	0
<b>Nervous system disorders NEC</b>		
Brain stem syndrome	2	0
Central nervous system lesion	10	0
Cerebral disorder	9	0
Microglial nodules	1	0
Nervous system disorder	83	0
Neurotoxicity	5	0
Psychomotor skills impaired	4	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	9	0
Hemianopia homonymous	3	0
Quadrantanopia	1	0
Tunnel vision	23	0
<b>Neurological signs and symptoms NEC</b>		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	2	0
Dizziness	22667	0
Dizziness exertional	101	0
Dizziness postural	2174	1
Drooling	27	0
Exaggerated startle response	4	0
Fontanelle bulging	4	0
Head discomfort	768	0
Hyporesponsive to stimuli	4	0
Inability to crawl	2	0
Infant irritability	6	0
Intracranial hypotension	4	0
Meningism	3	0
Myoclonus	34	0
Neurological decompensation	4	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Neurological symptom	145	0
Patient elopement	3	0
Persistent postural-perceptual dizziness	43	0
Pleocytosis	4	0
Presyncope	620	0
Sensory overload	11	0
Slow response to stimuli	8	0
Spontaneous cerebrospinal fluid leak syndrome	2	0
Tongue biting	10	0
Unresponsive to stimuli	109	0
<b>Neuromuscular disorders NEC</b>		
Hypotonic-hyporesponsive episode	1	0
Muscle contractions involuntary	40	0
Muscle spasticity	34	0
Neuromuscular pain	6	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Sensorimotor disorder	1	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	21	0
Myasthenia gravis crisis	3	0
<b>Olfactory nerve disorders</b>		
Anosmia	363	0
Hyposmia	11	0
Parosmia	410	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	63	0
<b>Paraesthesias and dysaesthesias</b>		
Anaesthesia	3	0
Burning feet syndrome	34	0
Burning sensation	1045	0
Burning sensation mucosal	3	0
Dysaesthesia	17	0
Formication	85	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	5	0
Hemiparaesthesia	5	0
Hyperaesthesia	276	0
Hypoaesthesia	6148	0
Lhermitte's sign	4	0
Paraesthesia	9892	0
Reversed hot-cold sensation	1	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	37	0
Gait spastic	1	0
Hemiparesis	118	0
Hemiplegia	53	0
Monoparesis	119	0
Monoplegia	145	0
Paralysis	354	0
Paraparesis	6	0
Paraplegia	3	0
Paresis	9	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Peripheral nerve palsy	1	0
Peripheral paralysis	1	0
Postictal paralysis	3	0
Quadriparesis	3	0
Quadriplegia	4	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	162	0
Parkinson's disease	18	0
Parkinsonism	13	0
Reduced facial expression	9	0
Vascular parkinsonism	1	0
<b><i>Partial complex seizures</i></b>		
Dreamy state	21	0
Focal dyscognitive seizures	7	0
Temporal lobe epilepsy	5	0
<b><i>Partial simple seizures NEC</i></b>		
Autonomic seizure	1	0
Simple partial seizures	7	0
<b><i>Peripheral neuropathies NEC</i></b>		
Autoimmune neuropathy	3	0
Axonal and demyelinating polyneuropathy	1	0
Axonal neuropathy	2	0
Brachial plexopathy	1	0
Ischaemic neuropathy	2	0
Neuralgic amyotrophy	11	0
Neuritis	19	0
Neuropathy peripheral	287	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	3	0
Peripheral sensory neuropathy	18	0
Polyneuropathy	16	0
Small fibre neuropathy	4	0
Thoracic outlet syndrome	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Acute encephalitis with refractory, repetitive partial seizures	1	0
Alcoholic seizure	1	0
Atonic seizures	12	0
Change in seizure presentation	7	0
Clonic convulsion	10	0
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	2	0
Epilepsy	352	1
Epileptic aura	3	0
Febrile convulsion	92	0
Hypoglycaemic seizure	1	0
Migraine-triggered seizure	2	0
Myoclonic epilepsy	5	0
Partial seizures	60	0
Psychogenic seizure	5	0
Seizure	1391	3
Seizure anoxic	4	0
Seizure cluster	9	0
Seizure like phenomena	3	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Status epilepticus	29	2
Tonic clonic movements	3	0
Tonic convulsion	39	0
<b>Sensory abnormalities NEC</b>		
Ageusia	1117	0
Allodynia	63	0
Aura	26	0
Central pain syndrome	2	0
Complex regional pain syndrome	15	0
Decreased vibratory sense	1	0
Dysgeusia	2025	0
Electric shock sensation	113	0
Hypogeusia	7	0
Intercostal neuralgia	2	0
Loss of proprioception	6	0
Neuralgia	1515	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	19	0
Post herpetic neuralgia	14	0
Restless arm syndrome	15	0
Restless legs syndrome	409	0
Sensory disturbance	165	0
Sensory loss	252	0
Taste disorder	528	0
Vibratory sense increased	5	0
Visual perseveration	1	0
<b>Sleep disturbances NEC</b>		
Microsleep	3	0
Periodic limb movement disorder	2	0
Sleep deficit	53	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	463	0
Incoherent	20	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Repetitive speech	4	0
Slow speech	42	0
Speech disorder	136	0
Speech disorder developmental	1	0
<b>Spinal cord and nerve root disorders NEC</b>		
Acquired syringomyelia	1	0
Cauda equina syndrome	6	0
Myelopathy	6	0
Radicular pain	1	0
Radiculitis brachial	29	0
Radiculopathy	3	0
Spinal cord disorder	7	0
Spinal cord ischaemia	1	0
Spinal cord oedema	1	0
Subacute combined cord degeneration	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	43	3

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Cerebral mass effect	10	0
Encephalomalacia	1	0
Intracranial mass	4	0
White matter lesion	5	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	515	2
<b><i>Tremor (excl congenital)</i></b>		
Action tremor	4	0
Asterixis	1	0
Essential tremor	7	0
Head titubation	25	0
Intention tremor	1	0
Postural tremor	2	0
Resting tremor	8	0
Tremor	9855	1
<b><i>Trigeminal disorders</i></b>		
Numb chin syndrome	3	0
Trigeminal nerve disorder	7	0
Trigeminal neuralgia	148	0
Trigeminal neuritis	2	0
Trigeminal palsy	1	0
<b><i>Vagus nerve disorders</i></b>		
Vagus nerve paralysis	1	0
Vocal cord paralysis	5	0
<b><i>Vertigos NEC</i></b>		
Vertigo CNS origin	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>181290</b>	<b>215</b>

## Case Series Drug Analysis Print

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Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortion related conditions and complications</b></i>		
Anembryonic gestation	1	0
<i><b>Abortions not specified as induced or spontaneous</b></i>		
Abortion missed	1	0
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	227	2
<i><b>Foetal complications NEC</b></i>		
Haemorrhage foetal	1	0
<i><b>Foetal position and presentation abnormalities</b></i>		
Face presentation	1	0
<i><b>Gestational age and weight conditions</b></i>		
Low birth weight baby	1	0
Premature baby	2	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Haemorrhage in pregnancy	1	0
<i><b>High risk pregnancies</b></i>		
Pregnancy of unknown location	1	0
<i><b>Hypertension associated disorders of pregnancy</b></i>		
Pre-eclampsia	3	0
<i><b>Labour onset and length abnormalities</b></i>		
Precipitate labour	1	0
Premature labour	3	0
Premature rupture of membranes	2	0
Prolonged labour	1	0
<i><b>Maternal complications of delivery NEC</b></i>		
Traumatic delivery	1	0
<i><b>Maternal complications of labour NEC</b></i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	1	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Biochemical pregnancy	3	0
Decidual cast	3	0
Ectopic pregnancy	8	0
Hyperemesis gravidarum	2	0
Morning sickness	1	0
Pelvic girdle pain	2	0
Preterm premature rupture of membranes	1	0
Somatic symptom disorder of pregnancy	1	0
<i><b>Multiple pregnancies</b></i>		
Twin pregnancy	2	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Delivery	1	0
Labour pain	1	0
Live birth	2	0
Pregnancy	24	0
Uterine contractions during pregnancy	1	0
<i><b>Placental abnormalities (excl neoplasms)</b></i>		
Foetal vascular malperfusion	1	0
<i><b>Pregnancy complicated by maternal disorders</b></i>		
Gestational diabetes	6	0
Peripartum cardiomyopathy	1	0
<i><b>Stillbirth and foetal death</b></i>		
Stillbirth	5	5

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b> <small>Pregnancy conditions cont'd</small>		
<b><i>Umbilical cord complications</i></b>		
Umbilical cord around neck	1	0
<b><i>Unintended pregnancies</i></b>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	4	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	2	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>325</b>	<b>7</b>

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Reaction Name	Total	Fatal
<b><i>Counterfeit, falsified and substandard products</i></b>		
Suspected counterfeit product	2	0
<b><i>Device electrical issues</i></b>		
Device electrical impedance issue	1	0
Electromagnetic interference	1	0
<b><i>Device incompatibility issues</i></b>		
Patient-device incompatibility	2	0
<b><i>Device issues NEC</i></b>		
Device expulsion	3	0
Device issue	4	0
Device leakage	2	0
<b><i>Device malfunction events NEC</i></b>		
Device occlusion	1	0
Oversensing	36	0
Stent malfunction	1	0
Thrombosis in device	70	1
Undersensing	7	0
<b><i>Device physical property and chemical issues</i></b>		
Needle issue	11	0
Syringe issue	1	0
<b><i>Manufacturing facilities and equipment issues</i></b>		
Manufacturing equipment issue	1	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	1	0
Suspected product contamination	1	0
<b><i>Product distribution and storage issues</i></b>		
Product temperature excursion issue	5	0
<b><i>Product label issues</i></b>		
Product barcode issue	1	0
Product label issue	2	0
<b><i>Product packaging issues</i></b>		
Product container issue	2	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	1	0
Product after taste	8	0
Product colour issue	4	0
Product leakage	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	8	0
<b><i>Product quality issues NEC</i></b>		
Product formulation issue	1	0
Product origin unknown	3	0
Product quality issue	1	0
Suspected product quality issue	2	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	4	0
<b>null SOC TOTAL</b>	<b>193</b>	<b>1</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	26	0
Behaviour disorder	1	0
Breath holding	5	0
Sexually inappropriate behaviour	1	0
Staring	14	0
<b><i>Abnormal food elimination</i></b>		
Self-induced vomiting	1	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	6	0
Adjustment disorder with mixed anxiety and depressed mood	2	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	14	0
Blunted affect	1	0
Constricted affect	16	0
Flat affect	11	0
Inappropriate affect	18	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	6	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	5	0
Generalised anxiety disorder	5	0
Neurosis	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	211	0
Anxiety	1334	0
Immunisation anxiety related reaction	2	0
Nervousness	610	0
Procedural anxiety	1	0
Stress	169	0
Tension	73	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	21	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	19	0
Antisocial behaviour	2	0
Asocial behaviour	1	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	2	0
Homicidal ideation	1	0
Impatience	2	0
Indifference	10	0
Paranoia	43	0
Personality change	10	0
Social avoidant behaviour	7	0
Soliloquy	3	0
Violence-related symptom	3	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	8	0
Bipolar disorder	6	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Change in sustained attention	1	0
Daydreaming	17	0
Distractibility	2	0
Mental fatigue	497	0
<b>Communications disorders</b>		
Communication disorder	9	0
Mutism	6	0
Speech sound disorder	2	0
<b>Confusion and disorientation</b>		
Confusional state	2197	0
Disorientation	745	0
<b>Decreased physical activity levels</b>		
Catatonia	3	0
<b>Deliria</b>		
Delirium	487	0
Delirium febrile	3	0
<b>Delusional disorders</b>		
Alice in wonderland syndrome	3	0
<b>Delusional symptoms</b>		
Delusion	54	0
Delusion of parasitosis	3	0
Mixed delusion	1	0
Thought withdrawal	1	0
<b>Dementia NEC</b>		
Pseudodementia	1	0
<b>Depressive disorders</b>		
Agitated depression	4	0
Childhood depression	1	0
Depression	703	0
Depression suicidal	16	0
Major depression	24	0
Menopausal depression	2	0
Mixed anxiety and depressive disorder	3	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	20	0
Dissociation	79	0
Dissociative amnesia	1	0
Dissociative disorder	2	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	44	0
Insomnia	3156	0
Middle insomnia	73	0
Terminal insomnia	27	0
<b>Dyssomnias</b>		
Dyssomnia	5	0
Poor quality sleep	673	0
<b>Eating disorders NEC</b>		
Binge eating	1	0
Eating disorder	19	0
Pica	1	0
Selective eating disorder	2	0
<b>Emotional and mood disturbances NEC</b>		
Anger	90	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Dysphoria	2	0
Emotional disorder	102	0
Emotional distress	88	0
Emotional poverty	2	0
Euphoric mood	69	0
Frustration tolerance decreased	15	0
Irritability	324	0
Mood altered	90	0
<b>Factitious disorders</b>		
Factitious disorder	4	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Acrophobia	2	0
Agoraphobia	5	0
Fear	71	0
Fear of death	18	0
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	5	0
Fear of injection	2	0
Fear of open spaces	1	0
Fear-related avoidance of activities	3	0
Performance fear	1	0
Phobia	3	0
Phonophobia	5	0
Social anxiety disorder	1	0
Social fear	1	0
Thanatophobia	1	0
<b>Fluctuating mood symptoms</b>		
Mood swings	145	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	945	0
Hallucination, auditory	49	0
Hallucination, olfactory	14	0
Hallucination, tactile	1	0
Hallucination, visual	59	0
Hallucinations, mixed	9	0
Somatic hallucination	1	0
<b>Impulse control disorders</b>		
Clinomania	1	0
Impulse-control disorder	3	0
Impulsive behaviour	2	0
Intermittent explosive disorder	1	0
<b>Increased physical activity levels</b>		
Restlessness	491	0
<b>Infancy, childhood and adolescence psychiatric disorders NEC</b>		
Emotional disorder of childhood	1	0
<b>Learning disorders</b>		
Reading disorder	2	0
<b>Mental disorders NEC</b>		
Mental disorder	30	0
Mental status changes	5	0
<b>Mental disorders due to a general medical condition NEC</b>		
Mental disorder due to a general medical condition	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Neuropsychiatric symptoms	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Anhedonia	4	0
Decreased interest	17	0
Depressed mood	707	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	20	0
Negative thoughts	11	0
Sense of a foreshortened future	3	0
Tearfulness	104	0
<b><i>Mood alterations with manic symptoms</i></b>		
Hypomania	1	0
Mania	31	0
<b><i>Mood disorders NEC</i></b>		
Affective disorder	4	0
Apathy	79	0
Laziness	2	0
Listless	125	0
Mood disorder due to a general medical condition	1	0
Substance-induced mood disorder	1	0
<b><i>Narcolepsy and associated conditions</i></b>		
Hypnagogic hallucination	4	0
Sleep attacks	2	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Body dysmorphic disorder	2	0
Compulsive shopping	2	0
Dermatillomania	2	0
Obsessive thoughts	3	0
Obsessive-compulsive disorder	2	0
Obsessive-compulsive symptom	1	0
<b><i>Orgasmic disorders and disturbances</i></b>		
Anorgasmia	6	0
Female orgasmic disorder	1	0
Orgasm abnormal	1	0
Orgasmic sensation decreased	4	0
Premature ejaculation	3	0
<b><i>Panic attacks and disorders</i></b>		
Limited symptom panic attack	1	0
Panic attack	355	0
Panic disorder	9	0
Panic reaction	42	0
<b><i>Paraphilias and paraphilic disorders</i></b>		
Fetishism	2	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	370	0
Abnormal sleep-related event	2	0
Confusional arousal	3	0
Exploding head syndrome	7	0
Nightmare	468	0
Parasomnia	1	0
Rapid eye movements sleep abnormal	4	0
Sleep inertia	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Sleep talking	16	0
Sleep terror	63	0
Sleep-related eating disorder	2	0
Somnambulism	11	0
<b>Perception disturbances NEC</b>		
Autoscopy	28	0
Deja vu	4	0
Delusional perception	2	0
Derealisation	18	0
Flashback	3	0
Illusion	12	0
Imperception	1	0
Jamais vu	1	0
Near death experience	1	0
Pseudohallucination	1	0
Time perception altered	6	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	4	0
<b>Psychiatric elimination disorders</b>		
Enuresis	62	0
<b>Psychiatric symptoms NEC</b>		
Decreased eye contact	2	0
Helplessness	3	0
Hypervigilance	12	0
Psychiatric symptom	14	0
Psychological trauma	5	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	6	0
Psychotic behaviour	2	0
Psychotic disorder	47	0
Psychotic symptom	1	0
Rebound psychosis	1	0
<b>Schizoaffective and schizophreniform disorders</b>		
Schizoaffective disorder	1	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	5	0
<b>Sexual desire disorders</b>		
Excessive masturbation	1	0
Hypersexuality	1	0
Libido decreased	25	0
Libido disorder	1	0
Libido increased	9	0
Loss of libido	54	0
<b>Sexual dysfunction NEC</b>		
Genito-pelvic pain/penetration disorder	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	444	0
Sleep disorder due to a general medical condition	1	0
Sleep disorder due to general medical condition, insomnia type	3	0
<b>Somatic symptom disorders</b>		
Conversion disorder	36	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Habit cough	39	0
Illness anxiety disorder	1	0
Psychogenic tremor	2	0
Somatic symptom disorder	1	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	22	0
Logorrhoea	3	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	36	0
Lack of spontaneous speech	3	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	35	0
Head banging	48	0
Waxy flexibility	2	0
<b><i>Stress disorders</i></b>		
Acute stress disorder	4	0
Burnout syndrome	15	0
Catastrophic reaction	1	0
Hyperarousal	3	0
Post-traumatic stress disorder	16	0
<b><i>Substance related and addictive disorders</i></b>		
Alcohol abuse	2	0
Alcohol use disorder	3	0
Alcoholic hangover	1	0
Alcoholism	3	0
Dependence	2	0
Drug abuse	1	0
Drug dependence	1	0
Nicotine dependence	1	0
Substance abuse	2	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Completed suicide	4	4
Intentional self-injury	9	0
Self-injurious ideation	3	0
Suicidal behaviour	4	0
Suicidal ideation	119	0
Suicide attempt	31	0
Suicide threat	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	95	0
Confabulation	1	0
Illogical thinking	1	0
Impaired reasoning	3	0
Intrusive thoughts	6	0
Morbid thoughts	5	0
Tachyphrenia	23	0
Thinking abnormal	31	0
Thought blocking	7	0
<b><i>Tic disorders</i></b>		
Secondary tic	2	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Tic	22	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>18171</b>	<b>4</b>

## Case Series Drug Analysis Print

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Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	8	0
Bladder irritation	7	0
Bladder pain	66	0
Bladder spasm	1	0
Dysuria	89	0
Incontinence	94	0
Micturition disorder	4	0
Micturition frequency decreased	1	0
Micturition urgency	102	0
Mixed incontinence	1	0
Pollakiuria	303	0
Stress urinary incontinence	1	0
Urethral pain	6	0
Urge incontinence	2	0
Urinary hesitation	7	0
Urinary incontinence	131	0
Urinary retention	101	0
Urine flow decreased	23	0
<i><b>Bladder disorders NEC</b></i>		
Bladder dilatation	1	0
Bladder disorder	23	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	17	1
Urinary bladder rupture	1	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	11	0
Cystitis noninfective	3	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Urinary tract disorder	12	0
Urogenital haemorrhage	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	2	0
Glomerulonephritis	1	0
Glomerulonephritis membranoproliferative	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	5	0
IgA nephropathy	4	0
Nephrotic syndrome	19	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Atonic urinary bladder	1	0
Automatic bladder	1	0
Bladder dysfunction	13	0
Hypertonic bladder	16	0
Loss of bladder sensation	13	0
Neurogenic bladder	4	0
<i><b>Nephritis NEC</b></i>		
Lupus nephritis	2	0
Nephritis	7	0
Tubulointerstitial nephritis	7	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
Renal & urinary disorders cont'd		
Nephropathy	2	0
<b>Renal disorders NEC</b>		
Oedematous kidney	1	0
Renal disorder	15	0
Renal haemorrhage	3	0
<b>Renal failure and impairment</b>		
Acute kidney injury	71	1
Anuria	5	0
Chronic kidney disease	11	0
End stage renal disease	1	0
Oliguria	11	0
Renal failure	49	2
Renal impairment	29	0
Renal injury	9	1
<b>Renal hypertension and related conditions</b>		
Hypertensive nephropathy	1	0
<b>Renal lithiasis</b>		
Nephrolithiasis	22	0
<b>Renal obstructive disorders</b>		
Hydronephrosis	1	0
<b>Renal structural abnormalities and trauma</b>		
Kidney enlargement	1	0
Renal atrophy	2	0
<b>Renal vascular and ischaemic conditions</b>		
Renal artery occlusion	2	0
Renal artery thrombosis	1	0
Renal cortical necrosis	1	0
Renal embolism	1	0
Renal infarct	17	1
Renal ischaemia	1	0
Renal tubular injury	1	0
Renal vascular thrombosis	2	0
Renal vasculitis	2	0
Renal vein embolism	1	0
Renal vein occlusion	3	0
Renal vein thrombosis	9	0
<b>Structural and obstructive urethral disorders (excl congenital)</b>		
Urethral spasm	1	0
Urethral stenosis	1	0
<b>Ureteric disorders NEC</b>		
Ureteral disorder	2	0
<b>Urinary abnormalities</b>		
Chromaturia	110	0
Glycosuria	1	0
Haematuria	1	0
Haematuria	67	0
Microalbuminuria	1	0
Proteinuria	12	0
Urine abnormality	21	0
Urine odour abnormal	22	0
<b>Urinary tract signs and symptoms NEC</b>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	59	0

# Case Series Drug Analysis Print

## Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
Renal & urinary disorders cont'd		
Nocturia	23	0
Polyuria	34	0
Renal colic	4	0
Renal pain	948	0
Urinary tract discomfort	2	0
Urinary tract pain	16	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2717</b>	<b>6</b>

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	12	0
<i><b>Breast disorders NEC</b></i>		
Anisomastia	1	0
Breast disorder	4	0
Breast enlargement	11	0
Breast mass	76	0
Gynaecomastia	10	0
Mammary duct ectasia	1	0
Nipple disorder	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	4	0
Nipple inflammation	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	9	0
Breast discolouration	1	0
Breast discomfort	12	0
Breast engorgement	6	0
Breast haemorrhage	1	0
Breast induration	1	0
Breast oedema	1	0
Breast pain	501	0
Breast swelling	73	0
Breast tenderness	78	0
Nipple exudate bloody	1	0
Nipple pain	38	0
Nipple swelling	4	0
<i><b>Cervix disorders NEC</b></i>		
Cervical friability	1	0
Cervix haemorrhage uterine	1	0
Ectropion of cervix	2	0
<i><b>Cervix neoplasms</b></i>		
Cervical polyp	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation delayed	2	0
Ejaculation disorder	4	0
Ejaculation failure	4	0
Erectile dysfunction	98	0
Erection increased	7	0
Organic erectile dysfunction	20	0
Painful ejaculation	1	0
Painful erection	2	0
Priapism	3	0
Retrograde ejaculation	4	0
Spontaneous penile erection	4	0
<i><b>Fallopian tube and ovary infections and inflammations</b></i>		
Noninfective oophoritis	1	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	3	0
Galactostasis	2	0
Lactation disorder	2	0
Lactation puerperal increased	6	0
Suppressed lactation	27	0

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Menopausal effects NEC</i></b>		
Artificial menopause	2	0
Menopausal disorder	3	0
Menopausal symptoms	64	0
Menopause delayed	5	0
Premature menopause	50	0
<b><i>Menopausal effects on the genitourinary tract</i></b>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	304	0
<b><i>Menstruation and uterine bleeding NEC</i></b>		
Abnormal uterine bleeding	9	0
Abnormal withdrawal bleeding	5	0
Dysmenorrhoea	1460	0
Intermenstrual bleeding	705	0
Menstrual discomfort	16	0
Menstrual disorder	1554	0
Menstruation irregular	2363	0
Premenstrual dysphoric disorder	6	0
Premenstrual headache	12	0
Premenstrual pain	86	0
Premenstrual syndrome	59	0
Retrograde menstruation	4	0
Withdrawal bleed	14	0
<b><i>Menstruation with decreased bleeding</i></b>		
Amenorrhoea	611	0
Hypomenorrhoea	439	0
Menstruation delayed	3264	0
Oligomenorrhoea	119	0
<b><i>Menstruation with increased bleeding</i></b>		
Heavy menstrual bleeding	4727	0
Menometrorrhagia	17	0
Polymenorrhoea	703	0
<b><i>Ovarian and fallopian tube cysts and neoplasms</i></b>		
Ovarian cyst	33	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	43	0
<b><i>Ovarian and fallopian tube disorders NEC</i></b>		
Fallopian tube spasm	1	0
Ovarian adhesion	1	0
Ovarian enlargement	3	0
Ovarian failure	4	0
Ovarian haemorrhage	5	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	1	0
Ovarian necrosis	1	0
Ovarian oedema	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	62	0
Premature ovulation	8	0
<b><i>Pelvic prolapse conditions</i></b>		
Vaginal prolapse	2	0
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Adnexa uteri pain	44	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Pelvic haematoma	1	0
Pelvic haemorrhage	27	0
Pelvic organ prolapse	1	0
<b><i>Penile and scrotal infections and inflammations</i></b>		
Balanoposthitis	4	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Penile blister	6	0
Penile burning sensation	1	0
Penile curvature	4	0
Penile discharge	4	0
Penile erosion	1	0
Penile exfoliation	1	0
Penile haemorrhage	7	0
Penile oedema	3	0
Penile pain	2	0
Penile size reduced	2	0
Penis disorder	10	0
Peyronie's disease	4	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	6	0
<b><i>Prostatic neoplasms and hypertrophy</i></b>		
Benign prostatic hyperplasia	2	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatic pain	1	0
Prostatism	1	0
Prostatomegaly	3	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Female genital tract fistula	1	0
Genital blister	5	0
Genital dysaesthesia	1	0
Genital haemorrhage	33	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	2	0
Genital lesion	2	0
Genital paraesthesia	5	0
Genital ulceration	13	0
Perineal disorder	2	0
Varicose veins pelvic	1	0
<b><i>Reproductive tract infections and inflammations NEC</i></b>		
Genital tract inflammation	2	0
<b><i>Reproductive tract neoplasms NEC</i></b>		
Genital cyst	2	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
Genital burning sensation	8	0
Genital discomfort	3	0
Genital erythema	1	0
Genital pain	4	0
Genital rash	6	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	179	0
Perineal pain	2	0
Pruritus genital	9	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b>Scrotal disorders NEC</b>		
Scrotal dermatitis	1	0
Scrotal oedema	1	0
Scrotal pain	19	0
Scrotal swelling	6	0
Varicocele	1	0
<b>Sexual function and fertility disorders NEC</b>		
Dyspareunia	7	0
Female sexual dysfunction	1	0
Infertility	14	0
Infertility female	7	0
Infertility male	3	0
Male sexual dysfunction	2	0
Sexual dysfunction	15	0
<b>Spermatogenesis and semen disorders</b>		
Aspermia	2	0
Haemospermia	18	0
Semen discolouration	2	0
<b>Testicular and epididymal disorders NEC</b>		
Testicular atrophy	1	0
Testicular disorder	9	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	113	0
Testicular retraction	3	0
Testicular swelling	24	0
Testis discomfort	6	0
<b>Testicular and epididymal infections and inflammations</b>		
Orchitis noninfective	1	0
<b>Testicular and epididymal neoplasms</b>		
Epididymal cyst	1	0
Testicular cyst	1	0
<b>Uterine disorders NEC</b>		
Adenomyosis	14	0
Endometrial hyperplasia	1	0
Endometrial thickening	3	0
Endometriosis	90	0
Metrorrhoea	1	0
Uterine enlargement	2	0
Uterine haemorrhage	72	0
Uterine pain	10	0
<b>Uterine neoplasms</b>		
Uterine cyst	1	0
Uterine polyp	4	0
<b>Uterine tone disorders</b>		
Uterine spasm	24	0
<b>Vaginal and vulval infections and inflammations</b>		
Vulvovaginal inflammation	2	0
<b>Vulvovaginal cysts and neoplasms</b>		
Bartholin's cyst	3	0
Vaginal cyst	15	0
Vulva cyst	1	0
<b>Vulvovaginal disorders NEC</b>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Vaginal disorder	1	0
Vaginal haemorrhage	1316	0
Vaginal ulceration	7	0
Vulval disorder	3	0
Vulval haemorrhage	34	0
Vulval ulceration	7	0
Vulvovaginal disorder	1	0
Vulvovaginal ulceration	2	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Clitoral engorgement	1	0
Coital bleeding	7	0
Enlarged clitoris	1	0
Labia enlarged	2	0
Vaginal discharge	90	0
Vaginal lesion	7	0
Vaginal odour	7	0
Vulval oedema	1	0
Vulvovaginal burning sensation	11	0
Vulvovaginal discomfort	10	0
Vulvovaginal dryness	13	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	39	0
Vulvovaginal pruritus	12	0
Vulvovaginal rash	3	0
Vulvovaginal swelling	7	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>20324</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	13	0
Apnoeic attack	1	0
Cheyne-Stokes respiration	2	0
Dyspnoea	7875	0
Dyspnoea at rest	15	0
Dyspnoea exertional	59	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	101	0
Hypopnoea	234	0
Hypoventilation	1	0
Irregular breathing	28	0
Mouth breathing	8	0
Orthopnoea	3	0
Respiration abnormal	111	0
Respiratory arrest	28	0
Respiratory distress	13	0
Respiratory fatigue	7	0
Sleep apnoea syndrome	32	0
Tachypnoea	39	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial haemorrhage	1	0
Bronchial secretion retention	2	0
Bronchiectasis	16	0
<i><b>Bronchospasm and obstruction</b></i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	646	0
Asthma exercise induced	4	0
Asthma late onset	3	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	2	0
Asthmatic crisis	5	0
Bronchial oedema	1	0
Bronchitis chronic	2	0
Bronchospasm	18	0
Chronic obstructive pulmonary disease	51	4
Cough variant asthma	9	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	644	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	3	0
Hypercapnia	1	0
Hypoxia	71	1
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	8	0
Cough	4019	0
Haemoptysis	144	0
Productive cough	213	0
Sputum discoloured	15	0
Sputum increased	3	0
Sputum retention	1	0
<i><b>Diaphragmatic disorders</b></i>		

## Case Series Drug Analysis Print

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Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Diaphragmatic paralysis	1	0
Diaphragmatic spasm	2	0
<b><i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i></b>		
Reflux laryngitis	4	0
Vocal cord disorder	5	0
Vocal cord dysfunction	7	0
Vocal cord thickening	2	0
<b><i>Laryngeal spasm, oedema and obstruction</i></b>		
Epiglottic oedema	1	0
Laryngeal oedema	3	0
Laryngospasm	3	0
Stridor	22	0
<b><i>Lower respiratory tract inflammatory and immunologic conditions</i></b>		
Alveolitis	2	0
Autoimmune lung disease	1	0
Eosinophilic pneumonia	2	0
Hypersensitivity pneumonitis	1	0
Pneumonitis	34	1
Pulmonary sarcoidosis	2	0
Pulmonary vasculitis	1	0
<b><i>Lower respiratory tract signs and symptoms</i></b>		
Hiccups	48	0
Lower respiratory tract congestion	4	0
Lung opacity	7	0
Pleuritic pain	48	0
Pulmonary haemorrhage	8	1
Pulmonary pain	234	0
Rales	2	0
<b><i>Mediastinal disorders</i></b>		
Pulmonary hilum mass	1	0
<b><i>Nasal congestion and inflammations</i></b>		
Nasal congestion	475	0
Nasal inflammation	8	0
Rhinitis allergic	28	0
Rhinitis perennial	1	0
<b><i>Nasal disorders NEC</i></b>		
Epistaxis	2289	0
Intranasal hypoaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	7	0
Nasal dryness	70	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	16	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	4	0
<b><i>Neonatal hypoxic conditions</i></b>		
Gasping syndrome	2	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Paranasal sinus disorders (excl infections and neoplasms)</i></b>		
Allergic sinusitis	2	0
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	4	0
Sinonasal obstruction	12	0
Sinus congestion	90	0
Sinus disorder	19	0
Sinus polyp	3	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Atelectasis	7	0
Cystic lung disease	1	0
Emphysema	5	0
Idiopathic pulmonary fibrosis	3	0
Interstitial lung disease	9	2
Lung consolidation	9	0
Lung cyst	1	0
Lung induration	1	0
Lung infiltration	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary calcification	1	0
Pulmonary cavitation	3	0
Pulmonary fibrosis	11	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Oropharyngeal swelling	2	0
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	36	0
Pharyngeal swelling	304	0
Pharyngeal ulceration	15	0
Tonsillar disorder	1	0
Tonsillar erythema	7	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	65	0
Tonsillar inflammation	4	0
Tonsillar ulcer	2	0
Tonsillolith	1	0
<b><i>Pleural conditions NEC</i></b>		
Pleural thickening	1	0
<b><i>Pleural infections and inflammations</i></b>		
Lupus pleurisy	2	0
Pleurisy	54	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Haemothorax	1	0
Pleural effusion	51	1
Pneumothorax	14	0
Pneumothorax spontaneous	2	0
<b><i>Pulmonary hypertension</i></b>		
Pulmonary hypertension	6	1
<b><i>Pulmonary oedemas</i></b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Acute lung injury	1	0
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	22	0
Pulmonary oedema	41	1
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary artery thrombosis	3	0
Pulmonary embolism	1713	112
Pulmonary infarction	15	1
Pulmonary thrombosis	31	5
Pulmonary venous thrombosis	4	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Acute respiratory failure	3	1
Respiratory failure	28	3
<b><i>Respiratory signs and symptoms NEC</i></b>		
Allergic respiratory symptom	11	0
Diaphragmalgia	16	0
Nasal flaring	1	0
Painful respiration	12	0
Pleural rub	1	0
Respiratory symptom	25	0
Suffocation feeling	5	0
Use of accessory respiratory muscles	3	0
<b><i>Respiratory tract disorders NEC</i></b>		
Allergic respiratory disease	1	0
Aspiration	10	2
Chronic respiratory disease	2	1
Lung disorder	12	0
Pulmonary mass	9	0
Respiratory disorder	8	0
Respiratory tract congestion	10	0
Respiratory tract haemorrhage	2	0
Respiratory tract irritation	10	0
Respiratory tract oedema	3	0
<b><i>Thoracic musculoskeletal disorders</i></b>		
Respiratory muscle weakness	2	0
<b><i>Tracheal disorders (excl infections and neoplasms)</i></b>		
Tracheal fistula	1	0
Tracheal pain	4	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	123	0
Catarrh	68	0
Choking	22	0
Choking sensation	13	0
Dry throat	261	0
Dysphonia	177	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	22	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	114	0
Nasal obstruction	2	0
Oropharyngeal blistering	27	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	42	0
Oropharyngeal pain	4235	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	78	0
Rhinalgia	35	0
Rhinorrhoea	1692	0
Sinus pain	608	0
Sneezing	526	0
Snoring	6	0
Throat clearing	8	0
Throat irritation	216	0
Throat lesion	1	0
Throat tightness	234	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	29	0
Yawning	73	0
<b><i>Vascular pulmonary disorders NEC</i></b>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>29289</b>	<b>137</b>

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### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	150	0
Acne cystic	11	0
Acne varioliformis	1	0
Dermatitis acneiform	12	0
<b><i>Alopecias</i></b>		
Alopecia	470	0
Alopecia areata	51	0
Alopecia scarring	2	0
Alopecia totalis	3	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	5	0
Hypotrichosis	1	0
Lichen planopilaris	1	0
Madarosis	6	0
<b><i>Angioedemas</i></b>		
Angioedema	363	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	2	0
Cold sweat	1731	0
Hidradenitis	4	0
Hyperhidrosis	9280	0
Hypohidrosis	6	0
Miliaria	224	0
Night sweats	1932	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<b><i>Bullous conditions</i></b>		
Autoimmune blistering disease	1	0
Blister	655	0
Blister rupture	7	0
Blood blister	114	0
Bullous haemorrhagic dermatosis	1	0
Dermatitis bullous	19	0
Dermatitis herpetiformis	2	0
Erythema multiforme	40	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	35	0
Pemphigus	9	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	0
<b><i>Connective tissue disorders</i></b>		
Chronic cutaneous lupus erythematosus	1	0
Cutaneous lupus erythematosus	3	0
Dermatomyositis	6	0
Subacute cutaneous lupus erythematosus	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	4	0
Dermatosis	1	0

## Case Series Drug Analysis Print

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Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
Skin disorders cont'd		
Dry skin	468	0
Macule	13	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	945	0
Papule	127	0
Scab	32	0
Scar discomfort	1	0
Scar pain	19	0
Sensitive skin	599	0
Skin burning sensation	588	0
Skin discolouration	227	0
Skin discomfort	6	0
Skin disorder	48	0
Skin fissures	17	0
Skin fragility	3	0
Skin indentation	18	0
Skin induration	18	0
Skin laxity	1	0
Skin lesion	62	0
Skin necrosis	7	0
Skin odour abnormal	51	0
Skin plaque	3	0
Skin reaction	277	0
Skin sensitisation	90	0
Skin swelling	101	0
Skin texture abnormal	2	0
Skin tightness	44	0
Skin warm	585	0
Skin weeping	10	0
Sticky skin	9	0
Target skin lesion	2	0
Transient acantholytic dermatosis	2	0
Yellow skin	33	0
<b><i>Dermatitis and eczema</i></b>		
Autoimmune dermatitis	2	0
Dermatitis	198	0
Dermatitis allergic	329	0
Dermatitis atopic	43	0
Dermatitis contact	36	0
Dermatitis diaper	3	0
Dyshidrotic eczema	21	0
Eczema	386	0
Eczema asteatotic	21	0
Eczema nummular	5	0
Eczema weeping	2	0
Hand dermatitis	7	0
Intertrigo	3	0
Neurodermatitis	2	0
Perioral dermatitis	5	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	13	0

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin irritation	162	0
Stasis dermatitis	7	0
Urticarial dermatitis	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	38	0
Drug reaction with eosinophilia and systemic symptoms	13	0
Fixed eruption	8	0
Palmar-plantar erythrodysesthesia syndrome	3	0
<b><i>Erythemas</i></b>		
Erythema	3427	0
Erythema ab igne	1	0
Palmar erythema	7	0
Plantar erythema	3	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	9	0
Exfoliative rash	20	0
Skin exfoliation	195	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Granuloma annulare	10	0
Granuloma skin	1	0
<b><i>Hyperkeratoses</i></b>		
Hyperkeratosis	2	0
Lichenoid keratosis	1	0
<b><i>Hyperpigmentation disorders</i></b>		
Chloasma	2	0
Ephelides	1	0
Melanoderma	2	0
Skin hyperpigmentation	10	0
Solar lentigo	7	0
<b><i>Hypertrichoses</i></b>		
Hypertrichosis	4	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	10	0
Skin hypopigmentation	3	0
Vitiligo	35	0
<b><i>Lipodystrophies</i></b>		
Lipoatrophy	2	0
Lipohypertrophy	2	0
Progressive facial hemiatrophy	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Anonychia	1	0
Ingrowing nail	2	0
Nail bed bleeding	2	0
Nail bed disorder	2	0
Nail bed inflammation	1	0
Nail bed tenderness	2	0
Nail discolouration	16	0
Nail disorder	4	0
Nail growth abnormal	3	0
Nail hypertrophy	1	0
Nail necrosis	1	0
Nail pigmentation	2	0

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### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Nail pitting	1	0
Nail ridging	9	0
Onychalgia	7	0
Onychoclasia	12	0
Onycholysis	4	0
Onychomadesis	5	0
Splinter haemorrhages	6	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	38	0
Panniculitis	4	0
<b><i>Papulosquamous conditions</i></b>		
Erythema annulare	2	0
Lichen planus	41	0
Lichen sclerosus	8	0
Lichen striatus	1	0
Parapsoriasis	2	0
Pityriasis lichenoides et varioliformis acuta	1	0
Pityriasis rosea	69	0
Pityriasis rubra pilaris	2	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photodermatosis	2	0
Photosensitivity reaction	172	0
Polymorphic light eruption	6	0
Solar dermatitis	1	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	17	0
<b><i>Pilar disorders NEC</i></b>		
Hair colour changes	16	0
Hair disorder	2	0
Hair growth abnormal	9	0
Hair texture abnormal	14	0
Piloerection	101	0
Pseudofolliculitis	2	0
Trichodynia	7	0
Trichorrhexis	7	0
<b><i>Pruritus NEC</i></b>		
Itching scar	5	0
Pruritus	8385	0
Pruritus allergic	1	0
Senile pruritus	1	0
<b><i>Psoriatic conditions</i></b>		
Dermatitis psoriasiform	2	0
Erythrodermic psoriasis	2	0
Guttate psoriasis	30	0
Nail psoriasis	1	0
Palmoplantar pustulosis	3	0
Psoriasis	256	0
Pustular psoriasis	7	0
<b><i>Purpura and related conditions</i></b>		
Ecchymosis	5	0
Henoch-Schonlein purpura	18	0
Petechiae	380	0
Purpura	149	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Pustular conditions</i></b>		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	8	0
Nodular rash	1	0
Rash	9217	0
Rash erythematous	2281	0
Rash macular	780	0
Rash maculo-papular	69	0
Rash morbilliform	50	0
Rash papular	576	0
Rash pruritic	1985	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	107	0
Systemic lupus erythematosus rash	9	0
<b><i>Rosaceas</i></b>		
Erythematotelangiectatic rosacea	3	0
Granulomatous rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	49	0
<b><i>Scaly conditions</i></b>		
Dandruff	2	0
Pityriasis	13	0
<b><i>Sebaceous gland disorders</i></b>		
Sebaceous glands overactivity	1	0
Seborrhoea	16	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Cellulite	3	0
Cutaneous symptom	11	0
Skin discharge	1	0
Skin mass	46	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Diabetic foot	2	0
Diabetic ulcer	1	0
Ischaemic skin ulcer	1	0
Pyoderma gangrenosum	3	0
Skin erosion	58	0
Skin ulcer	37	0
Vasculitic ulcer	1	0
<b><i>Skin cysts and polyps</i></b>		
Dermal cyst	27	0
<b><i>Skin dystrophies</i></b>		
Keloid scar	3	0
Skin wrinkling	6	0
<b><i>Skin haemorrhages</i></b>		
Haemorrhage subcutaneous	21	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	52	0
<b><i>Skin hyperplasias and hypertrophies</i></b>		
Skin hypertrophy	4	0
<b><i>Skin hypoplasias and atrophies</i></b>		

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Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin atrophy	12	0
Skin striae	13	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	5	0
Needle track marks	3	0
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	3	0
Leukoplakia	1	0
<b>Skin vascular conditions NEC</b>		
Angiodermatitis	1	0
Haemangioma-thrombocytopenia syndrome	1	0
Skin oedema	3	0
<b>Skin vasculitides</b>		
Capillaritis	1	0
Cutaneous vasculitis	15	0
Hypersensitivity vasculitis	4	0
Nodular vasculitis	1	0
Vasculitic rash	29	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	59	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	5	0
Telangiectasia	5	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	7	0
Cold urticaria	10	0
Idiopathic urticaria	10	0
Mechanical urticaria	9	0
Solar urticaria	1	0
Urticaria	2634	0
Urticaria cholinergic	1	0
Urticaria chronic	53	0
Urticaria contact	3	0
Urticaria papular	3	0
Urticaria pigmentosa	1	0
Urticaria thermal	7	0
Urticarial vasculitis	5	0
<b>Skin disorders SOC TOTAL</b>	<b>52868</b>	<b>0</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<b><i>Age related issues</i></b>		
Childhood	1	0
Menarche	3	0
Menopause	78	0
Postmenopause	18	0
<b><i>Alcohol product use</i></b>		
Alcoholic	4	0
<b><i>Crime victims</i></b>		
Victim of abuse	1	0
<b><i>Criminal activity</i></b>		
Chemical submission	1	0
Verbal abuse	1	0
<b><i>Dependents</i></b>		
Sick relative	1	0
<b><i>Dietary and nutritional issues</i></b>		
Inadequate diet	1	0
Kosher diet	1	0
<b><i>Disability issues</i></b>		
Bedridden	99	0
Breast prosthesis user	2	0
Corrective lens user	1	0
Dependence on oxygen therapy	1	0
Disability	9	0
Hearing aid user	3	0
Hearing disability	1	0
Housebound	2	0
Immobile	57	0
Immobilisation prolonged	4	0
Impaired driving ability	6	0
Impaired work ability	33	0
Loss of personal independence in daily activities	15	0
Mental disability	1	0
Paralytic disability	1	0
Physical disability	3	0
Sight disability	26	0
Sitting disability	3	0
Walking aid user	2	0
Walking disability	9	0
Wheelchair user	3	0
<b><i>Educational issues</i></b>		
Educational problem	1	0
Illiteracy	3	0
<b><i>Employment issues</i></b>		
Job dissatisfaction	2	0
Retirement	5	0
Stress at work	1	0
Unemployment	1	0
<b><i>Family and partner issues</i></b>		
Homosexual parent	1	0
Partner stress	1	0
<b><i>Non-occupational and unspecified environmental problems</i></b>		
Food contamination	1	0
Water pollution	4	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Social circumstances</b> <small>Social circumstances cont'd</small>		
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	9	0
<i><b>Sexuality issues</b></i>		
Anal sex	1	0
Homosexuality	1	0
<i><b>Social issues NEC</b></i>		
Blood donor	2	0
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
Hair dye user	1	0
Impaired quality of life	5	0
Refusal of treatment by patient	1	0
Refusal of vaccination	3	0
Tanning	2	0
Tattoo	1	0
<i><b>Tobacco use</b></i>		
Non-tobacco user	6	0
Tobacco user	2	0
<b>Social circumstances SOC TOTAL</b>	<b>449</b>	<b>0</b>

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Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i><b>Anaesthesia and allied procedures</b></i>		
Local anaesthesia	3	0
Nerve block	5	0
<i><b>Analgesia supportive care</b></i>		
Analgesic therapy	2	0
<i><b>Antiinfective therapies</b></i>		
Antibiotic therapy	2	0
COVID-19 treatment	7	0
<i><b>Arterial therapeutic procedures (excl aortic)</b></i>		
Cerebral revascularisation	1	0
Coronary artery bypass	2	0
<i><b>Autonomic nerve therapeutic procedures</b></i>		
Vagotomy	3	0
<i><b>Biliary tract and gallbladder therapeutic procedures</b></i>		
Cholecystectomy	2	0
Cholelithotomy	1	0
<i><b>Blood and blood product treatment</b></i>		
Photopheresis	1	0
Transfusion	1	0
<i><b>Breast therapeutic procedures NEC</b></i>		
Axillary lymphadenectomy	1	0
<i><b>Bronchial and pulmonary therapeutic procedures</b></i>		
Airway secretion clearance therapy	1	0
Antitussive therapy	1	0
<i><b>Cardiac device therapeutic procedures</b></i>		
Cardiac pacemaker insertion	2	0
Pacemaker generated rhythm	1	0
<i><b>Cardiac therapeutic procedures NEC</b></i>		
Pericardial excision	2	0
<i><b>Cardiac valve therapeutic procedures</b></i>		
Aortic valve replacement	1	0
Heart valve replacement	1	0
<i><b>Chemotherapies</b></i>		
Chemotherapy toxicity attenuation	1	0
<i><b>Contraceptive methods female</b></i>		
Contraception	3	0
Contraceptive diaphragm	3	0
Intrauterine contraception	1	0
Oral contraception	2	0
<i><b>Corneal and scleral therapeutic procedures</b></i>		
Corneal transplant	2	0
<i><b>Dental and gingival therapeutic procedures</b></i>		
Dental care	1	0
Tooth extraction	2	0
Tooth restoration	4	0
<i><b>Dietary and nutritional therapies</b></i>		
Fluid replacement	1	0
Gluten free diet	1	0
Medical diet	6	0
Mineral supplementation	1	0
Nothing by mouth order	8	0
<i><b>External ear therapeutic procedures</b></i>		
Cerumen removal	2	0

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Surgical &amp; medical procedures cont'd</i>		
<b><i>Eye therapeutic procedures NEC</i></b>		
Eye irrigation	3	0
<b><i>Facial therapeutic procedures</i></b>		
Face lift	3	0
<b><i>Fallopian tube therapeutic procedures</i></b>		
Fallopian tube operation	1	0
<b><i>Fascial and bursal therapeutic procedures</i></b>		
Bursa removal	1	0
<b><i>Fertility and fertilisation interventions female</i></b>		
Ovulation induction	2	0
<b><i>Gastric therapeutic procedures</i></b>		
Antacid therapy	1	0
<b><i>Gastrointestinal therapeutic procedures NEC</i></b>		
Intestinal resection	1	0
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	28	0
<b><i>Gynaecological therapeutic procedures NEC</i></b>		
Gynaecological disorder prophylaxis	1	0
Menstrual cycle management	6	0
<b><i>Haematological therapeutic procedures NEC</i></b>		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	1	0
<b><i>Head, neck and oral cavity therapeutic procedures NEC</i></b>		
Neck lift	1	0
<b><i>Hormonal therapeutic procedures NEC</i></b>		
Hormone replacement therapy	7	0
Hormone therapy	9	0
Steroid therapy	1	0
<b><i>Immunisations</i></b>		
COVID-19 immunisation	225	0
Immunisation	118	0
Influenza immunisation	1	0
Tuberculosis immunisation	1	0
<b><i>Induced abortions</i></b>		
Abortion induced	3	0
<b><i>Iris and ciliary body therapeutic procedures</i></b>		
Pupil constriction procedure	1	0
<b><i>Joint therapeutic procedures</i></b>		
Hip surgery	1	0
Joint dislocation reduction	1	0
Joint injection	6	0
Joint stabilisation	2	0
Knee operation	2	0
Shoulder operation	3	0
<b><i>Large intestine therapeutic procedures</i></b>		
Appendectomy	9	0
Colectomy	2	0
<b><i>Limb therapeutic procedures</i></b>		
Arm amputation	1	0
Foot amputation	1	0
Leg amputation	6	0
Limb immobilisation	28	0

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Surgical &amp; medical procedures cont'd</i>		
Limb operation	14	0
Limb reattachment surgery	1	0
Toe amputation	5	0
<b>Mastectomies</b>		
Breast conserving surgery	2	0
<b>Muscle therapeutic procedures</b>		
Muscle relaxant therapy	3	0
<b>Nail therapeutic procedures</b>		
Nail operation	2	0
<b>Nasal therapeutic procedures</b>		
Nasal irrigation	1	0
<b>Nervous system therapeutic procedures NEC</b>		
Central nervous system stimulation	3	0
Multiple sclerosis relapse prophylaxis	1	0
Neurological rehabilitation	1	0
<b>Orbit and globe therapeutic procedures</b>		
Eye muscle operation	1	0
<b>Patient positioning</b>		
Prone position	1	0
<b>Peripheral nerve therapeutic procedures</b>		
Carpal tunnel decompression	1	0
<b>Phototherapies</b>		
UV light therapy	1	0
<b>Prophylactic procedures NEC</b>		
Anaphylaxis prophylaxis	3	0
Reproductive system disorder prophylaxis	1	0
<b>Psychiatric therapies</b>		
Antidepressant therapy	1	0
Psychotherapy	1	0
<b>Renal therapeutic procedures</b>		
Dialysis	1	0
<b>Respiratory tract therapeutic procedures NEC</b>		
Asthma prophylaxis	1	0
Respiratory therapy	1	0
<b>Skin and subcutaneous tissue therapeutic procedures NEC</b>		
Dermal filler injection	1	0
<b>Skin lesion excisions</b>		
Skin neoplasm excision	1	0
Tattoo excision	1	0
<b>Skull and brain therapeutic procedures</b>		
Brain operation	2	0
<b>Small intestine therapeutic procedures</b>		
Ileostomy	3	0
<b>Spine and spinal cord therapeutic procedures</b>		
Spinal operation	1	0
<b>Testicular and scrotal therapeutic procedures</b>		
Testes exploration	1	0
<b>Therapeutic procedures NEC</b>		
Anaphylaxis treatment	4	0
Antiallergic therapy	1	0
Bed rest	25	0
Catheter management	4	0
Catheter placement	2	0

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Surgical &amp; medical procedures cont'd</i>		
Continuous passive motion machine therapy	1	0
Fatigue management	1	0
Heat therapy	3	0
Hospitalisation	31	0
Immobilisation bandage	1	0
Injection	55	0
Interchange of vaccine products	55	0
Localised alternating hot and cold therapy	6	0
Magnetic therapy	2	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	3	0
Occupational therapy	1	0
Physical fitness training	4	0
Physiotherapy	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Rehabilitation therapy	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Stoma care	1	0
Surgery	2	0
Therapeutic hypothermia	2	0
Therapy change	2	0
Transgender operation	1	0
Tumour excision	1	0
Wound treatment	1	0
<b><i>Tonsillar therapeutic procedures</i></b>		
Tonsillectomy	1	0
<b><i>Tracheal therapeutic procedures</i></b>		
Tracheostomy	1	0
<b><i>Tumour vaccine therapies</i></b>		
Tumour vaccine therapy	1	0
<b><i>Uterine therapeutic procedures</i></b>		
Endometrial ablation	6	0
Hysterectomy	1	0
<b><i>Vascular therapeutic procedures NEC</i></b>		
Clamping of blood vessel	1	0
Thrombectomy	4	0
Thromboembolectomy	1	0
Thrombolysis	2	0
Vascular graft	1	0
<b><i>Venous therapeutic procedures</i></b>		
Phlebotomy	2	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>864</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Accelerated hypertension	1	0
Hypertensive crisis	15	0
Hypertensive emergency	2	0
Hypertensive urgency	4	0
Malignant hypertension	7	0
Tyramine reaction	1	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Aneurysm	13	1
Aneurysm ruptured	1	0
Artery dissection	4	0
Venous aneurysm	1	0
<b><i>Aortic aneurysms and dissections</i></b>		
Acute aortic syndrome	1	0
Aortic aneurysm	7	0
Aortic aneurysm rupture	1	1
Aortic dissection	4	1
Aortic intramural haematoma	1	0
Penetrating aortic ulcer	1	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	25	1
Aortic thrombosis	13	2
<b><i>Aortic infections and inflammations</i></b>		
Aortitis	2	0
<b><i>Aortic necrosis and vascular insufficiency</i></b>		
Aortic occlusion	1	0
Aortic stenosis	3	0
<b><i>Arterial infections and inflammations</i></b>		
Arteritis	5	0
Giant cell arteritis	61	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	25	0
Labile blood pressure	5	0
<b><i>Bruising, ecchymosis and purpura</i></b>		
Achenbach syndrome	10	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	132	2
Distributive shock	2	0
Hypoperfusion	2	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	4	0
Shock	59	1
Shock haemorrhagic	1	0
Shock symptom	6	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	16	0
Haematoma	115	0
Haemorrhage	1475	2
Internal haemorrhage	31	0
Venous haemorrhage	9	0
<b><i>Lymphangiopathies</i></b>		
Lymphangiopathy	2	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Lymphocele	2	0
Lymphorrhoea	1	0
<b>Lymphoedemas</b>		
Lymphoedema	79	0
<b>Non-site specific embolism and thrombosis</b>		
Air embolism	1	0
Arterial thrombosis	32	1
Atheroembolism	1	0
Embolism	255	3
Embolism arterial	4	0
Embolism venous	13	1
Microembolism	3	0
Paradoxical embolism	1	0
Post thrombotic syndrome	4	0
Thrombophlebitis migrans	2	0
Thrombosis	1890	41
Venous thrombosis	37	0
<b>Non-site specific necrosis and vascular insufficiency NEC</b>		
Arterial occlusive disease	16	0
Arterial spasm	2	0
Arterial stenosis	1	0
Arteriosclerosis	9	0
Haemorrhagic infarction	1	0
Infarction	15	0
Ischaemia	15	0
Peripheral venous disease	11	0
Vascular compression	2	0
Vascular occlusion	3	0
Vasospasm	13	0
Venous occlusion	1	0
<b>Non-site specific vascular disorders NEC</b>		
Angiopathy	5	0
Arterial rupture	1	0
Capillary disorder	1	0
Capillary fragility	11	0
Collateral circulation	1	0
Haemodynamic instability	4	0
Hyperaemia	2	0
Neovascularisation	1	0
Superficial vein prominence	8	0
Vascular fragility	1	0
Vascular pain	136	0
Vascular rupture	2	0
Vascular wall discolouration	1	0
Vasodilatation	124	0
Vein collapse	2	0
Vein discolouration	8	0
Vein disorder	26	0
Vein rupture	17	0
<b>Peripheral aneurysms and dissections</b>		
Peripheral artery aneurysm	2	0
<b>Peripheral embolism and thrombosis</b>		
Axillary vein thrombosis	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Blue toe syndrome	41	0
Deep vein thrombosis	1284	9
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	28	0
Pelvic venous thrombosis	25	1
Peripheral artery thrombosis	20	0
Peripheral embolism	11	0
Peripheral vein thrombus extension	1	0
Subclavian artery embolism	2	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	72	0
Thrombophlebitis	143	0
Venous thrombosis limb	7	0
<b>Peripheral vascular disorders NEC</b>		
Cyanosis	112	0
Erythromelalgia	7	0
Flushing	712	0
Hot flush	2208	0
Peripheral vascular disorder	7	0
<b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b>		
Dry gangrene	2	0
Extremity necrosis	3	0
Iliac artery occlusion	2	0
Intermittent claudication	7	0
Ischaemic limb pain	5	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	5	0
Peripheral artery occlusion	9	0
Peripheral coldness	1330	0
Peripheral ischaemia	35	2
Poor peripheral circulation	58	0
Raynaud's phenomenon	156	0
<b>Phlebitis NEC</b>		
Phlebitis	64	0
Phlebitis superficial	13	0
<b>Site specific embolism and thrombosis NEC</b>		
Brachiocephalic vein thrombosis	1	0
<b>Site specific necrosis and vascular insufficiency NEC</b>		
Superior vena cava syndrome	1	0
<b>Site specific vascular disorders NEC</b>		
Aortic dilatation	1	0
Aortic rupture	1	0
Pallor	428	0
Plethoric face	1	0
<b>Varicose veins NEC</b>		
Bleeding varicose vein	2	0
Spider vein	21	0
Varicophlebitis	10	0
Varicose ulceration	1	0
Varicose vein	155	0
Varicose vein ruptured	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
<b><i>Vascular hypertensive disorders NEC</i></b>		
Diastolic hypertension	5	0
Essential hypertension	1	0
Hypertension	1033	0
Labile hypertension	2	0
Neurogenic hypertension	1	0
Systolic hypertension	3	0
Venous hypertension	4	0
White coat hypertension	12	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	16	0
Diastolic hypotension	1	0
Hypotension	558	0
Orthostatic hypotension	48	0
<b><i>Vascular malformations and acquired anomalies</i></b>		
Arteriovenous fistula	1	0
<b><i>Vasculitides NEC</i></b>		
Behcet's syndrome	3	0
Diffuse vasculitis	2	1
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	3	1
Vasculitis	111	2
<b><i>Vena caval embolism and thrombosis</i></b>		
Vena cava thrombosis	7	1
<b>Vascular disorders SOC TOTAL</b>	<b>13663</b>	<b>74</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>857702</b>	<b>1190</b>
<b>TOTAL REPORTS</b>	<b>242148</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>1190</b>